



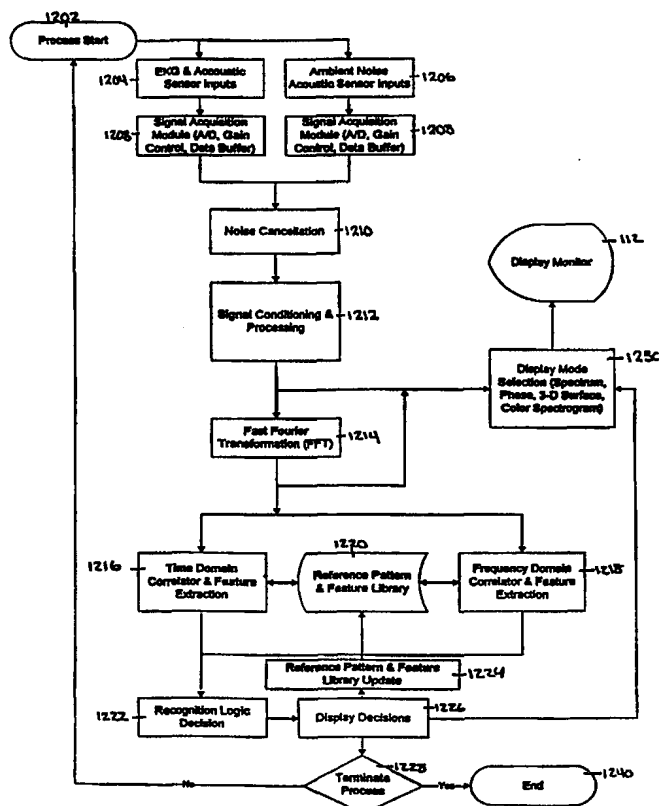
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 7/04		A1	(11) International Publication Number: WO 98/26716
			(43) International Publication Date: 25 June 1998 (25.06.98)
(21) International Application Number: PCT/US97/21917 (22) International Filing Date: 2 December 1997 (02.12.97) (30) Priority Data: 08/769,156 18 December 1996 (18.12.96) US (71)(72) Applicant and Inventor: MOHLER, Sailor [US/US]; 5410 Lightening View, Columbia, MD 21045 (US). (74) Agent: ROBERTS, Jon, L.; Roberts & Brownell, L.L.C., Suite 212, 8381 Old Courthouse Road, Vienna, VA 22182 (US).			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT

(57) Abstract

An apparatus detection of the second heart sound acoustic signature associated with heart valve closure includes a sensor assembly (102) comprising a housing (302; 402), an electronic module (314; 422), a shock dampener (316; 432; 434), a mounting means, a transducer (320; 432; 434), an acoustic coupling (322; 436; 438) and a back cover. The sensor assembly (102) is connected to a data acquisition module (103) which in turn is connected to a signal processing means (104), a remote connection means (110) and a monitor (112). An improved acoustic coupling (322; 436; 438) is disclosed that provides low-loss acoustic transmission between the skin of the patient and the sensor assembly (102).



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TITLE: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENTFIELD OF THE INVENTION

This invention relates generally to an apparatus, operation and method for measurement of blood pressure. In particular, this invention relates to an apparatus, operation and method for the detection, identification and characterization of sounds relating to either systemic or pulmonary blood pressure through the use of sonospectrography.

BACKGROUND OF THE INVENTION

Blood pressure is the force exerted by the blood against the inner walls of blood vessels. Blood pressure determination is an important diagnostic tool. The blood vessels that comprise the vascular system can be grouped into two main divisions, a systemic circuit and a pulmonary circuit. In the systemic circuit, high blood pressure may indicate the presence of arteriosclerosis or other vascular disease, while low blood pressure may indicate shock or blood loss. Detection and measurement of elevated pulmonary blood pressure is a key diagnostic indicator for a number of pulmonary diseases, such as: cystic fibrosis, pleuresy, lung pulmonary diseases, and pulmonary impedance. Early diagnosis of these diseases greatly assists in symptom mitigation and improved patient quality of life.

The systemic circuit includes the aorta and its branches that deliver oxygenated blood to all body tissues, as well as the companion system of veins returning blood to the right atrium. Freshly oxygenated blood received by the left atrium is forced into the systemic circuit by the contraction of the left ventricle. When the left ventricle contracts, the mitral valve closes, and the only exit is through the aortic valve into the aorta.

The peripheral nature of certain systemic circuit arteries in the body extremities allows for the traditional indirect measurement of the systolic and diastolic pressures with a sphygmomanometer blood pressure cuff. While this method is effective for many patients, use of the traditional blood pressure cuff on an extremity may be contraindicated for patients suffering from any number of problems including severe extremity trauma, or burns. In patients where use of the traditional blood pressure cuff is contraindicated, there is no reliable

1 alternative method of monitoring blood pressure. This is extremely important in trauma
2 patients where prompt detection of blood pressure changes are needed to counteract the
3 effects of shock or large blood loss.

4 The pulmonic circuit provides for blood circulation from the right ventricle through
5 the pulmonary valve into the pulmonary artery. The pulmonary artery extends upward and
6 posteriorly from the heart, dividing into right and left branches which serve the right and left
7 lungs, respectively. Within the lungs the right and left branches of the pulmonary artery
8 divide repeatedly giving rise to arterioles that continue into the capillary networks associated
9 with the walls of the alveoli. Gas exchange occurs as the blood moves through these
10 capillaries, so that when the blood enters the venules of the pulmonary circuit, it is well
11 oxygenated and poor in carbon dioxide. The pulmonary venules merge forming small veins,
12 which in turn converge forming larger veins. Four pulmonary veins return oxygenated blood
13 to the left atrium, thereby completing the pulmonic circuit.

14 None of the arteries of the pulmonic system are located in extremities and therefore
15 measurement of pulmonic system pressure with a blood pressure cuff is not possible.

16 At present, the only reliable method for measuring pulmonic system blood pressure is
17 through use of an invasive blood pressure catheter that is inserted directly into the pulmonary
18 artery. This diagnostic procedure has a substantial degree of risk and is expensive, its use is
19 thus generally seen as an unjustified procedure in patients without other symptoms.

20 The physician may attempt to detect and differentiate the abnormal sounds that occur
21 with elevated blood pressure using traditional auscultation. Closure of the aortic and
22 pulmonary semilunar heart valves generate a sound component that is in the audio frequency
23 range. As the systemic or pulmonic blood pressure increases, the frequency components of
24 the related heart valve also increase. This increased frequency audio component is not
25 present in a healthy patient. However, aural detection of this frequency increase is extremely
26 difficult because the physician must determine the absolute frequency of the audio component
27 of the heart valve of interest. Additionally, the sounds are very weak and heavily
28 contaminated with noise from other patient heart sounds, other normal patient body sounds
29 and external ambient noise in the room. Further, the audio component of the aortic and
30 pulmonary semilunar heart valves are heavily attenuated as they pass through the patient's
31 chest and chest wall.

1 A need exists for a non-invasive, low cost and reliable means for determining
2 systemic blood pressure in those situations where traditional means are contraindicated. A
3 need also exists for a non-invasive, low cost and reliable means for determining pulmonary
4 blood pressure.

5 6 DESCRIPTION OF RELATED ART

7
8 As mentioned, the sounds related to systemic and pulmonary heart pressure are
9 difficult to discern. United States Patent No. 4,528,690 to Sedgwick; United States Patent
10 No. 3,790,712 to Andries; and United States Patent No. 3,160,708 to Andries et al. disclose
11 relatively simple electronic stethoscopes as methods for amplification of the sounds in an
12 attempt to raise the sub-audible components into the audible range. However, simple
13 amplification of the entire frequency spectrum, as disclosed, does not help in determining the
14 absolute frequency of the heart valve sounds, or in detecting the subtle changes of this
15 frequency that occur with changes in blood pressure.

16 To this end, United States Patent No. 4,594,731 to Lewkowicz and United States
17 Patent No. 5,347,583 to Dieken et al. disclose various forms of selective filtering or signal
18 processing on the audio signal in the electronic stethoscope. Lewkowicz discloses a means
19 for shifting the entire detected spectrum of sounds upward while expanding the bandwidth so
20 that they are more easily perceived by the listener. Dieken et al. discloses an electronic
21 stethoscope having a greater volume of acoustic space and thereby improving low frequency
22 response.

23 The electronic stethoscope provides a moderate improvement over conventional
24 methods of auscultation. However, information remains in audio form only and is transient;
25 the physician is unable to visualize the data and either freeze the display or focus on a
26 particular element of the signal retrieved. To accommodate that deficiency, the technique of
27 phonocardiography, which is the mechanical or electronic registration of heart sounds with
28 graphic display, is used. United States Patent No. 5,218,969 to Bredesen et al.; United States
29 Patent No. 5,213,108 to Bredesen et al.; United States Patent No. 5,012,815 to Bennett, Jr. et
30 al.; United States Patent No. 4,967,760 to Bennett, Jr. et al.; United States Patent No.
31 4,991,581 to Andries; and United States Patent No. 4,679,570 to Lund et al. disclose

1 phonocardiography with signal processing and visual/audio output. United States Patent No.
2 5,301,679 to Taylor; and United States Patent No. 4,792,145 to Eisenberg et al. disclose
3 phonocardiography with signal processing and visual display.

4 The process of phonocardiography as commonly known in the art, acquires acoustic
5 data through an air conduction microphone strapped to a patients chest, and provides the
6 physician with a strip chart recording of this acoustic data. The strip chart is generally created
7 at a rate of 100 mm/second. As this method is generally used, with the exception of the
8 created strip chart, data is not stored. Thus, it is not possible to manipulate and/or process the
9 data post acquisition. In addition, phonocardiography does not provide the sensitivity needed
10 to monitor softer physiological sounds such as the closure of the semilunar valves and blood
11 flow through the circulatory system.

12 As previously noted, one problem in traditional auscultation is ambient noise from the
13 room in which the examination is occurring, which reduces the signal-to-noise ratio of the
14 sounds of interest. United States Patent No. 4,672,977 to Kroll discloses a method for
15 automatic lung sound cancellation and provides visual and audio output. United States Patent
16 No. 5,309,922 to Schechter et al. discloses a method for cancellation of ambient noise to
17 enhance respiratory sounds and provides visual and audio output. United States Patent No.
18 5,492,129 to Greenberger discloses a method for reducing general ambient noise and provides
19 audio output.

20 United States Patent No. 5,036,857 to Semmlow et al. discloses a method of
21 phonocardiography with piezoelectric transducer. Semmlow specifically recommends against
22 Fast Fourier Transformation analysis of the phonocardiography data and relies on processing
23 by other means. United States Patent No. 5,109,863 to Semmlow et al.; and United States
24 Patent No. 5,035,247 issued to Heimann also disclose piezoelectric transducers.

25 United States Patent No. 5,002,060 to Nedivi, discloses both heart and respiratory
26 sensors, with Fast Fourier Transformation analysis. In the technique disclosed by Nedivi the
27 sensors are not physically attached to the patient. Thus the sensors are not capable of
28 detecting the low intensity sound of the aortic and pulmonary semilunar heart valves.

29 Devices currently known in the art do not provide either a means of determining
30 systemic blood pressure where use of a blood pressure cuff is contraindicated, or a low risk,
31 non-invasive means of determining pulmonic blood pressure. Additionally, the related art

1 does not provide the level of aural sensitivity needed to reliably detect the sounds of the aortic
2 and pulmonary semilunar heart valves and determine the precise frequency of these sounds.

3 What is needed is a safe, sensitive and noninvasive means of measuring systemic
4 and/or pulmonic blood pressure. This is accomplished through the present invention.
5 Through the use of sonospectrography, a procedure based on integral spectral analysis
6 techniques, systemic pressure can be monitored in conditions where traditional auscultation is
7 contraindicated. Additionally, sonospectrography can be used to monitor pulmonic pressure
8 in an inexpensive, noninvasive and low risk manner, allowing for the early detection of
9 conditions such as cystic fibrosis, pleuresy, lung pulmonary diseases and pulmonary
10 impedance. Sonospectrography is defined as the separation and arrangement of the frequency
11 components of acoustic signals in terms of energy or time.

12 Further embodiments of the present invention provide a means of detecting
13 physiological sounds, such as sounds emitted by the heart and other body organs as well as
14 sounds related to the flow of blood through the circulatory system. Analysis of these sounds
15 can be used to determine systemic and pulmonary blood pressure, monitor anesthesiology,
16 determine cardiac output, monitor the circulation of diabetic individuals, and monitor fetal
17 heartbeat as well as detect conditions such as aneurysms, arterial occlusions, arthritic
18 decrepitation, phlebitis, venous thrombosis, intravascular blood clotting and carotid artery
19 disease.

20 21 SUMMARY OF THE INVENTION

22
23 It is therefore an object of the present invention to provide an apparatus, operation and
24 method for the detection and analysis of physiological sounds, such as sounds emitted by the
25 heart and other body organs as well as sounds related to the flow of blood through the
26 circulatory system.

27 It is a further object of the present invention to provide an apparatus, operation and
28 method to be used to determine systemic and pulmonary blood pressure, monitor
29 anesthesiology, determine cardiac output, monitor the circulation of diabetic individuals, and
30 monitor fetal heartbeat as well as detect conditions such as aneurysms, arterial occlusions,
31 arthritic decrepitation, phlebitis, venous thrombosis, intravascular clotting and carotid artery

1 disease.

2 It is a further object of the present invention to provide this apparatus, operation and
3 method through the use of sonospectrography.

4 It is a further object of the present invention to provide this apparatus, operation and
5 method through a synchronized and coordinated combination of sonospectrography and
6 electrocardiogram signals.

7 It is a further object of the present invention to provide this apparatus, operation and
8 method through visual display means that provide insight to the subtle characteristics of the
9 acoustic signature.

10 It is a further object of the present invention to provide this apparatus, operation and
11 method through selective time and frequency windowing of the acoustic signals.

12 It is a further object of the present invention to provide this apparatus, operation and
13 method through real-time signal processing or recorded-signal post processing.

14 It is a further object of the present invention to provide this apparatus, operation and
15 method through use of single or multiple transducers.

16 It is a further object of the present invention to provide this apparatus, operation and
17 method through a computer assisted search algorithm to identify optimal placement of the
18 transducer(s) on the patient's chest wall.

19 It is a further object of the present invention to provide this apparatus, operation and
20 method in office environments with moderate to high ambient noise levels, through adaptive
21 noise cancellation techniques.

22 It is a further object of the present invention to provide this apparatus, operation and
23 method in a form that provides for dynamic template building to facilitate disease detection
24 and identification.

25 It is a further object of the present invention to provide this apparatus, operation and
26 method through neural network techniques.

27 It is a further object of the present invention to provide an acoustic coupling that
28 minimizes signal loss between the subject-detector interface and allows for the detection of
29 sounds heretofore undetectable in a normal room environment.

30 It is a further object of the present invention to extend the ability of clinicians to
31 analyze sounds which are lower in amplitude than those detectable by the unaided ear.

1 It is a further object of the present invention to extend the ability of clinicians to
2 analyze sounds which are lower in frequency than those detectable by typical auscultation
3 techniques.

4 It is a further object of the present invention to increase detection of a specified
5 frequency range through the use of a tailored bandpass amplifier.

6 It is a further object of the present invention to provide a means for data storage, data
7 manipulation and data transmission.

8 It is a further object of the present invention to provide this apparatus, operation and
9 method through advanced processing of acoustic signatures in the time and frequency domain
10 to isolate and display the sound components associated with pulmonary and/or aortic heart
11 valve closure.

12 It is a further object of the present invention to provide an apparatus, operation and
13 method that is suitable for routine physical examination screening and early diagnosis of
14 elevated pulmonic blood pressure thereby providing an opportunity for early intervention to
15 enhance the patient's productive life.

16 It is a further object of the present invention to provide an apparatus, operation and
17 method that is suitable for monitoring of systemic blood pressure in patients where use of a
18 traditional blood pressure cuff is contraindicated.

19 These and other objects of the present invention will become obvious to those skilled
20 in the art upon review of the following disclosure.

21 An apparatus for determining blood pressure in accordance with the present invention
22 includes a sensor assembly comprising a housing, an electronic module, a shock dampener, a
23 mounting means, a piezoelectric transducer, an acoustic coupling and a back cover. The
24 sensor assembly is connected to a data acquisition module which in turn is connected to a
25 signal processing means. The signal processing means is connected to an electronic storage
26 means, a hard copy reproduction means, a remote connection means and a monitor. In an
27 alternative embodiment of the invention a plurality of sensor assemblies are connected to the
28 data acquisition module. In another alternative embodiment of the invention a means for
29 determining an electrocardiogram is connected to the signal processing means. In yet another
30 alternative embodiment of the invention, data acquisition module is connected to high-fidelity
31 earphones.

1 The operation for determining blood pressure in accordance with the present invention
2 includes:

- 3 1) performing start-up procedures;
- 4 2) acquiring physiologic signals;
- 5 3) acquiring ambient or background signals;
- 6 4) processing and subtracting ambient signals from physiologic signals;
- 7 5) conditioning and processing resultant data;
- 8 6) subjecting the conditioned and processed data to Fast Fourier Transformation;
- 9 7) passing the time domain components of the data through a time domain
10 correlator and feature extraction process;
- 11 8) passing the frequency domain components of the data through a frequency
12 domain correlator and feature extraction process;
- 13 9) comparing the time domain output and the frequency domain output to a
14 reference pattern and feature library;
- 15 10) determining whether the time domain output and frequency domain output
16 match known disease modalities;
- 17 11) determining whether a disease modality is indicated;
- 18 12) updating the reference pattern and feature library; and
- 19 13) providing the information regarding the disease modality to the physician so
20 that a
21 treatment regimen may commence.

22 The method for determining blood pressure in accordance with the present invention
23 includes monitoring the sounds of the aortic and/or the pulmonary semilunar valves. Where
24 one wishes to determine systemic pressure, the aortic semilunar valve is monitored. This is
25 done by placing the acoustic coupling of the sensor assembly adjacent to the patient's skin at
26 the traditional auscultation point for the aortic valve. Where one wishes to monitor
27 pulmonary pressure, the pulmonary semilunar valve is monitored. This is done by placing the
28 acoustic coupling of the sensor assembly in contact with the patient's skin at the traditional
29 auscultation point for the pulmonic valve. Detected signals are manipulated in the same
30 fashion noted in the "operation" of the present invention. The signals may be viewed and
31 analyzed by medical personnel at any number of points during this data manipulation process

1 to allow for the implementation of a treatment regimen. Where the sound emitted by either
2 semilunar valve is of a higher than normal frequency, this is indicative of increased blood
3 pressure in the corresponding circuit; that is, an increased frequency emitted by the aortic
4 semilunar valve is indicative of higher than normal systemic blood pressure, while an
5 increased frequency being emitted by the pulmonary semilunar valve is indicative of higher
6 than normal pulmonary blood pressure.

8 BRIEF DESCRIPTION OF THE DRAWINGS

9
10 Figure 1 is a schematic representation of the overall architecture and user interface of
11 the present invention.

12 Figure 2a depicts an exploded, oblique view of the sensor assembly.

13 Figure 2b depicts an exploded, side view of the sensor assembly.

14 Figure 3 depicts an exploded, oblique view of an alternative embodiment of the sensor
15 assembly.

16 Figure 4 depicts a circuit diagram of the electronic module, data cable and data
17 acquisition module.

18 Figure 5 depicts a circuit diagram of greater detail, comprising the electronic module,
19 data cable and data acquisition module.

20 Figure 6 depicts a circuit diagram of still greater detail, comprising the electronic
21 module, data cable and data acquisition module.

22 Figure 7 depicts the frequency response of a tailored bandpass amplifier.

23 Figure 8 illustrates the simultaneous display of ECG and acoustic signal data.

24 Figure 9a illustrates an acoustic amplitude vs. time display mode.

25 Figure 9b illustrates a relative amplitude vs. frequency display mode.

26 Figure 9c illustrates a frequency vs. time display mode.

27 Figure 10 is a flow chart illustrating the operation of the present invention.

28 Figure 11 graphs the relationship of second heart sound frequency vs. blood pressure.

30 DETAILED DESCRIPTION

31

The present invention provides an apparatus, operation and method to passively and non-invasively measure systemic and pulmonic blood pressure through detection, identification and characterization of the acoustic signature associated with heart valve closure.

APPARATUS

Referring to Figure 1, the overall architecture of the present invention is described. Patient physiologic signals, such as acoustic vibrations or electrical impulses, are detected by sensor assembly **102**. In an alternative embodiment a plurality of sensor assemblies can be used to either simultaneously obtain signals from various locations of the body or to simultaneously obtain signals from both the patient and the environment. Sensor assembly **102** is connected to data acquisition means **103**.

Data acquisition means **103** comprises preamplifier **114**, audio amplifier **116**, and analog-to-digital converter **118**. Preamplifier **114** electronically isolates the transducer, detects the electronic signals, and sends them to audio amplifier **116** and to analog-to-digital converter **118**. Audio amplifier **116** drives one or more sets of high-fidelity earphones **120**. Analog-to-digital converter **118** samples the analog signal and converts it to a binary number for each time sample. Data acquisition means **103** is connected to signal processing means **104**.

Signal processing means **104** is a general-purpose microprocessor. Signal processing means **104**, also has means for video display of information, such as monitor **112**. Signal processing means **104** is connected to electronic data storage means **106**, operator input means **107**, hard copy reproduction means **108** and remote connection means **110**.

Various types of electronic data storage are known to those skilled in the art. In alternative embodiments electronic data storage means **106** comprises: internal hard disk drive, external hard disk drive, floppy disks, digital audio tape, magneto-optical storage or CD ROM. Likewise, various types of operator input means are known to those skilled in the art. In alternative embodiments operator input means **107** comprises: keyboard, mouse, voice detector or other means. Hard copy reproduction means **108** provides copies of images displayed on monitor **112** for purposes such as maintaining medical records, assisting

1 consultations, and assisting data processing and review. Remote connection means **110** is a
2 modem. In alternative embodiments, the system of the present invention may be directly
3 linked to a network via a network interface card or other suitable means. Thus a modem may
4 not always be necessary.

5 In an alternative sensor assembly embodiment, sensor assembly **102** can detect both
6 physiologic and background signals. In another alternative sensor assembly embodiment, one
7 side of sensor assembly **102** comprises an audio transducer which is in contact with the skin
8 while a second audio transducer on the opposite side faces away from the patient. This
9 second transducer is designed to acquire ambient sounds in synchronism with the sounds
10 reaching the transducer in contact with the patient's skin to reject common mode signals
11 reaching both transducers. By adding the environmental signals out of phase with the signals
12 acquired from the patient, the sounds in common to both transducers are effectively canceled.
13 In yet another alternative sensor assembly embodiment the target frequency range for data
14 acquisition is about 200 to 2000 Hz. In another alternative sensor assembly embodiment, the
15 target frequency range for signal acquisition is about 400 hertz.

16 In an alternative preamplifier embodiment, preamplifier **114** demonstrates low-noise
17 data acquisition and proper impedance matching.

18 In an alternative analog-to-digital converter embodiment analog-to-digital converter
19 **118** has a sample rate about 4 to 48 Khz. In yet another alternative analog-to-digital converter
20 embodiment, analog-to-digital converter **118** has a sample rate of about 44 Khz. In another
21 alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a
22 resolution of about 16 bits. In yet another alternative analog-to-digital converter embodiment,
23 analog-to-digital converter **118** has a linearity about ± 0.005 percent of full scale. In another
24 alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a
25 sample length of about one to sixty seconds. In yet another alternative analog-to-digital
26 converter embodiment, analog-to-digital converter **118** has an operator selectable sample
27 length.

28 In an alternative earphones embodiment, earphones **120** have separate volume
29 controls.

30 In an alternative signal processing means embodiment, signal processing means **104** is
31 a computer with a central processing unit. In another alternative signal processing means

embodiment, signal processing means **104** is an IBM compatible personal computer using an INTEL processor (386, 486, Pentium), having a minimum of 8 MB RAM memory and a minimum hard disk size of 500 MB. In yet another alternative signal processing means embodiment, signal processing means **104** is a Macintosh PowerPC.

In an alternative monitor embodiment, monitor **112** has a minimum display size of 600 X 400 pixels and a minimum monitor **112** display depth of eight bits. In yet another alternative monitor embodiment, monitor **112** is a high resolution EGA or VGA color display monitor.

In an alternative signal processing means embodiment, signal processing means **104** comprises a sound card. In another alternative signal processing means embodiment, the sound card comprises a "Tahiti" multiple channel computer sound card manufactured by Turtle Beach, although sound cards such as the Pro Audio 1b (Media Vision) can also be used.

In an alternative hard copy reproduction means embodiment, hard copy reproduction means **108**, is a printer. In another alternative hard copy reproduction means embodiment, hard copy reproduction means **108** is a printer capable of generating a variety of different graphic displays. In yet another alternative hard copy reproduction means embodiment, hard copy reproduction means **108** is a laser printer.

In an alternative remote connection means embodiment, remote connection means **110** is an internal or external, high speed modem. In another alternative remote connection means embodiment, remote connection means **110** has a speed of at least 14.4 kilobytes per second.

Referring to Figure 2a, an oblique view of an embodiment of sensor assembly **102** is shown. Figure 2b depicts a side view of an embodiment of sensor assembly **102**. Housing **302** comprises a sound deadening material having sufficient mass to dampen high frequency ambient disturbances and hold the sensor assembly in contact with the patient through gravity. Housing **302** has housing front **304** and housing back **306**. Rim **308** is located on the periphery of housing front **304**. First indentation **310** runs parallel and adjacent to the inside of rim **308**. Second indentation **312** runs parallel and adjacent to the inside of first indentation **310**. Bore **312** is approximately centrally located within second indentation **312** and is shaped and sized in conformity to the shape and size of electronic module **314**.

1 Electronic module **314** nests within bore **312** of housing **302**. As will be further discussed,
2 signal detection and processing circuitry are incorporated within electronic module **314**.

3 Shock dampener **316** is positioned adjacent to first indentation **310**. Mounting means
4 **318** is positioned adjacent to shock dampener **316**. Transducer **320** is positioned within
5 mounting means **318**. Transducer **320** converts detected signals into electronic signals.
6 Acoustic coupling **322** is positioned adjacent to transducer **320**. Acoustic coupling **322**
7 serves to dilinearize excitation response and reduce dynamic range.

8 Once assembled, housing **302** is closed to the ambient environment with back cover
9 **324**. Sensor assembly **102** comprising all the individual sensor elements, is assembled and
10 sealed to form a single complete unit.

11 In an alternative housing embodiment, housing **302** is composed of nickel plated
12 aluminum, but can be any material having sufficient mass to dampen high frequency ambient
13 disturbances and hold the sensor in contact with the patient through gravity.

14 In an alternative sensor assembly embodiment, when electronic module **314** nests
15 within bore **312** of housing **302**, top **316** of electronic module **314** is flush with second
16 indentation **312**.

17 In an alternative shock dampener embodiment shock dampener **316** is an "O" ring.

18 In an alternative mounting means embodiment, mounting means **318** is a plastic
19 mounting ring.

20 In an alternative transducer embodiment, transducer **320** is a piezoelectric disk. In
21 another alternative transducer embodiment, transducer **320** has a high impedance. In yet
22 another alternative transducer embodiment, transducer **320** has an impedance of about 470
23 Kohms. In another alternative transducer embodiment, transducer **320** has high efficiency as
24 compared with conventional electromagnet type speakers. In yet another alternative
25 transducer embodiment, transducer **320** is ultra thin and lightweight. In another alternative
26 transducer embodiment, transducer **320** has a frequency range of about 500 - 20,000 Hz. In
27 yet another alternative transducer embodiment, transducer **320** has a capacitance at 120 Hz of
28 about 60 ± 30 % nF. In another alternative transducer embodiment, transducer **320** current
29 leakage is limited to about one micro ampere.

30 In an alternative acoustic coupling embodiment, acoustic coupling **322** is impedance
31 matched, and serves to provide a low-loss acoustic transmission coupling between the skin of

1 the patient and transducer 320, thereby minimizing signal loss across the subject-detector
2 interface. In another alternative acoustic coupling embodiment, acoustic coupling 322 is a
3 parametric acoustic transducer. In yet another acoustic coupling embodiment, acoustic
4 coupling 322 has a high conduction coefficient. In another alternative acoustic coupling
5 embodiment, acoustic coupling 322 is made of latex foam. In yet another alternative acoustic
6 coupling embodiment, acoustic coupling 322 is logarithmically attenuated, having low
7 transmission at low frequencies and high transmission at high frequencies.

8 Referring to Figure 3 an oblique exploded view of an alternative embodiment of
9 sensor assembly 102 is shown. Housing 402 comprises a sound deadening material having
10 sufficient mass to dampen high frequency ambient disturbances and hold the sensor assembly
11 in contact with the patient through gravity. Housing 402 has housing front 404 and housing
12 back 406. First rim 408 is located on the periphery of housing front 404. Second rim 410 is
13 located on the periphery of housing back 406. First indentation 412 runs parallel and adjacent
14 to the inside of first rim 408. Second indentation 414 runs parallel and adjacent to the inside
15 of first indentation 412. Third indentation 416 runs parallel and adjacent to the inside of
16 second rim 410. Fourth indentation 418 runs parallel and adjacent to the inside of third
17 indentation 416. First bore 420 is approximately centrally located within second indentation
18 414 and is shaped and sized in conformity to the shape and size of first electronic module
19 422. Second bore 440 is approximately centrally located within fourth indentation 418 and is
20 shaped and sized in conformity to the shape and size of second electronic module 442. First
21 electronic module 422 nests within first bore 420 of housing 402. Second electronic module
22 442 nests within second bore 440 of housing 402. As will be further discussed, signal
23 detection and processing circuitry are incorporated within first and second electronic module
24 422, 442.

25 First shock dampener 424 is positioned adjacent to first indentation 412. Second
26 shock dampener 426 is positioned adjacent to third indentation 416. First mounting means
27 428 is positioned adjacent to first shock dampener 424. Second mounting means 430 is
28 positioned adjacent to second shock dampener 426. First transducer 432 is positioned within
29 first mounting means 428. Second transducer 434 is positioned within second mounting
30 means 430. First transducer 432, converts detected physiologic signals into electronic
31 signals. Second transducer 434, converts detected environmental or background signals into

1 electronic signals. First acoustic coupling **436** is positioned adjacent to first transducer **432**.
2 Second acoustic coupling **438** is positioned adjacent to second transducer **434**. First and
3 second acoustic coupling **436**, **438** serve to dilinearize excitation response and reduce
4 dynamic range.

5 In an alternative housing embodiment, housing **402** is composed of nickel plated
6 aluminum.

7 In an alternative shock dampener embodiment, first and second shock dampener **424**,
8 **426** is an "O" ring.

9 In an alternative mounting means embodiment, first and second mounting means **428**,
10 **430** is a plastic mounting ring.

11 In an alternative transducer embodiment, first and second transducer **432**, **434** is a
12 piezoelectric disk. In another alternative transducer embodiment, first and second transducer
13 **432**, **434** has a high impedance. In yet another alternative transducer embodiment, first and
14 second transducer **432**, **434** has an impedance of about 470 Kohms. In another alternative
15 transducer embodiment, first and second transducer **434**, **434** has high efficiency as compared
16 with conventional electromagnet type speakers. In yet another alternative transducer
17 embodiment, first and second transducer **432**, **434** is ultra thin and lightweight. In another
18 alternative transducer embodiment, first and second transducer **432**, **434** has a frequency
19 range of about 5 - 2,000 Hz. In yet another alternative transducer embodiment, first and
20 second transducer **432**, **434** has a capacitance at 120 Hz of about 60 ± 30 % nF. In another
21 alternative transducer embodiment, first and second transducer **432**, **434** current leakage is
22 limited to about one micro ampere.

23 In an alternative acoustic coupling embodiment, first and second acoustic coupling
24 **436**, **438**, is impedance matched, and serves to provide a low-loss acoustic transmission
25 coupling between the skin of the patient and first transducer **432**, thereby minimizing signal
26 loss across the subject-detector interface. In another alternative acoustic coupling
27 embodiment, first and second acoustic coupling **436**, **438** is a parametric acoustic
28 transconductor. In yet another acoustic coupling embodiment, first and second acoustic
29 coupling **436**, **438** has a high conduction coefficient. In another alternative acoustic coupling
30 embodiment, first and second acoustic coupling **436**, **438** is made of latex foam. In yet
31 another alternative acoustic coupling embodiment, acoustic coupling **322** is logarithmically

1 attenuated, having low transmission at low frequencies and high transmission at high
2 frequencies.

3 Referring to Figure 4, electronic module **314**, transducer **320**, data cable **502**, and data
4 acquisition module **504** of the present invention are shown in schematic form. In
5 combination, first resistor **506**, semiconductor device **508**, second resistor **510**, and first
6 capacitor **512** comprise electronic module **314**. Electronic module **314** performs functions
7 such as signal amplification, and filtering. Transducer **320** is connected in parallel with first
8 resistor **506**, second resistor **510**, first capacitor **512**, and semiconductor **508**. Semiconductor
9 **508** serves to modulate current. First capacitor **512** provides gain and source decoupling for
10 semiconductor **508**.

11 In an alternative first resistor embodiment, first resistor **506** provides a matching load
12 to transducer **320**. In another alternative first resistor embodiment first resistor **506** has a
13 resistance of 470 Kohms.

14 In an alternative second resistor embodiment, second resistor **510** is about 10 Kohms.

15 In an alternative semiconductor embodiment, semiconductor **508** is field effect
16 transistor. In another alternative semiconductor embodiment, semiconductor **508** is a field
17 effect transistor with an N-type base.

18 In an alternative first capacitor embodiment, first capacitor **512** is 60 microfarads and
19 is connected to ground.

20 Figure 5 depicts a circuit diagram of the electronic module, data cable and data
21 acquisition module in greater detail. The circuit comprises electronic module **314**, transducer
22 **320**, data cable **502**, and data acquisition module **504**. Data cable **502** couples electronic
23 module **314** to data acquisition module **504**. Data acquisition module **504** comprises an
24 amplifier. As depicted in Fig. 5, highpass filter **606** is followed by lowpass filter **608** having
25 a DC injection point. The amount of DC injection is made variable by value selection of
26 variable resistor **610**. In an alternative value selection embodiment, value selection is
27 determined by the practitioner. In yet another alternative value selection embodiment, value
28 selection is determined automatically by the signal processing means in conformity with
29 predetermined parameters.

30 In an alternative data cable embodiment, data cable **502** is twisted pair **602**, wherein
31 two insulated wires are twisted forming a flexible line without the use of spacers. In another

1 alternative data cable embodiment, data cable **502** is shielded pair **604**, wherein two parallel
2 conductors are separated from each other and surrounded by a solid dielectric. In this
3 alternative embodiment, the conductors are contained within a copper-braid tubing that acts
4 as a shield. The assembly is covered with a rubber or flexible composition coating to protect
5 the line against moisture and friction. There are two advantages of this alternative
6 embodiment: (1) the capacitance between each conductor and ground is uniform along the
7 entire length of the line; and (2) the wires are shielded against pickup of stray electric fields.
8 In yet another alternative embodiment shielded pair **604** data cable **502** is connected to sensor
9 housing **610** and to ground as a means for reducing electrical noise and increasing patient
10 safety.

11 In an alternative data acquisition module embodiment, data acquisition module **504**
12 has a low frequency response from about 10 Hz to a crossover point at 100 Hz, rising to a
13 level 20 dB higher from about 600 Hz to 2 KHZ, then declining steadily beyond that point. In
14 another alternative data acquisition module embodiment, data acquisition module **504**
15 comprises a voltage gain, variable from zero to fifty, allowing recovery of low-level sounds
16 from 600 to about 2000 Hz while preserving the ability to measure low-frequency signals
17 having a relatively high amplitude, without amplifier saturation.

18 In an alternative highpass filter embodiment, highpass filter **606** has a gain of about 7,
19 and lowpass filter **608** drives an output amplifier with a gain of about 7. In another
20 alternative highpass filter embodiment the overall voltage gain available with the gain
21 potentiometer at maximum will be about 50. An advantage of this alternative embodiment is
22 the ability to reject a narrow range of frequencies in a notch caused by the phase delay in the
23 components of highpass filter **606**. In an alternative highpass filter embodiment this notch is
24 set at 100 Hz. In another alternative highpass filter embodiment this notch is set at about 50 -
25 60 Hz, thereby providing a measure of hum rejection

26 Figure 6 depicts a circuit diagram of the electronic module, data cable and data
27 acquisition module in greater detail. The circuit comprises electronic module **314**, transducer
28 **320**, data cable **502**, and data acquisition module **504**. Three stage resistor/capacitor network
29 **702** gives a total of about 180 degrees of phase shift at a design frequency of about 100 Hz
30 that is related to the combined resistor/capacitor time constants of the network. Field effect
31 transistor **508** input is AC-coupled to the four-pole lowpass filter **608** formed by a single 747-

1 type operational amplifier pair.

2 Figure 7 depicts an idealized shape of an amplifier having low-frequency response
3 from first point **802** to crossover point **804** and having higher frequency response of
4 predetermined level **806**, from second point **808** to third point **810**. In an alternative
5 embodiment, first point **802** is about 10 Hz, crossover point **804** is about 100 Hz,
6 predetermined level **806** is about 20 dB, second point **808** is about 600 Hz and third point **810**
7 is about 2 KHz. In yet another alternative embodiment, crossover point **804** is about 60 Hz.

8 Figure 8 further depicts the response of the tailored bandpass amplifier, plotting
9 amplitude **902** vs. frequency **904** of basic heart sounds **906** and sounds of interest **908**. In
10 alternative embodiments, the response of sounds of interest **908** may be set at varying levels
11 **910**.

12 Figure 9 depicts the simultaneous display of electrocardiogram and sonospectrography
13 data. In the simultaneous display mode, the present invention provides for plotting
14 electrocardiogram data and sonospectrography data as a function of intensity **1002** and time
15 **1004**, with digital markers **1006** to allow the visual correlation of points of signal activity that
16 may be common to both signals. As an example, the electrocardiogram pulse at **1008** can be
17 visually correlated with a select part of the acoustic signal **1010** and differentially measured to
18 within 23 millionths of a second. This allows an operator who may be less familiar with
19 acoustic signatures to correlate the electrocardiogram signal, which may be well understood,
20 with the acoustic signal.

21 Referring to Figures 10a, 10b, and 10c, the display methodology of the present
22 invention is shown. The present invention provides a means to simultaneously display the
23 signal of interest in a variety of different forms. In Figure 10a, the signal of interest of the
24 present invention is presented as a simple time series, with acoustic amplitude **1102** on the
25 vertical scale and time **1104** on the horizontal scale. In Figure 10b, the signal of interest of
26 the present invention is presented as a time and frequency display, with relative amplitude
27 **1106** of each slice of the frequency spectrum on the vertical scale and frequency spectrum
28 **1108** on the horizontal display. In Figure 10c, the signal of interest of the present invention is
29 presented with frequency **1110** on the vertical axis, time **1112** on the horizontal axis, and
30 relative amplitude plotted in different color hues (not shown) and/or grey scale intensity.

31 Having thus described the basic concept of the apparatus of the invention, it will be

1 readily apparent to those skilled in the art that the foregoing detailed disclosure is intended to
2 be presented by way of example only, and is not limiting. Various alterations, improvements
3 and modifications will occur and are intended to those skilled in the art, but are not expressly
4 stated herein. For example, while cardiovascular monitoring is a key aspect of the invention,
5 the techniques described herein are equally applicable to the monitoring of other body organs
6 and regions of the body of both humans and animals and thus may also find utility in the
7 veterinary sciences. These modifications, alterations and improvements are intended to be
8 suggested hereby, and are within the spirit and scope of the invention.

10 OPERATION

11
12 Figure 11 depicts the operation of the apparatus of the present invention with
13 associated hardware and software. At step **1202**, start-up procedures are performed such as
14 initialization, calibration, sensor selection, patient parameter input, and buffer clearing,
15 among others. Upon completion of these start-up procedures steps **1204** and **1206** are
16 initiated. At step **1204**, sensor **102** provides patient physiologic signals for signal processing.
17 In an alternative embodiment, sensor **102** can include electrocardiogram sensors and acoustic
18 sensors. At step **1206** acoustic sensors are used to detect background or ambient noise.

19 Next, at step **1208**, the detected signals are passed to individual data acquisition
20 modules which contain means for signal filtering, impedance matching, amplification, and
21 buffering. These functions are performed by the components of the circuitry illustrated in
22 Figs. 4-6.

23 At step **1210**, the signals from the ambient noise acoustic sensor acquired in step
24 **1206**, are processed and subtracted from the signals from the desired sensor of step **1204** in a
25 noise cancellation process to reduce the effect of ambient noise from the patient's
26 environment.

27 At step **1212**, the signal undergoes additional signal conditioning and processing. The
28 purpose of this conditioning step is to convert the analog signal to digital, provide adjustable
29 decimation with a sampling rate suitable to avoid biasing, provide adjustable smoothing,
30 averaging and peak holding. In an alternative embodiment the signal conditioning and
31 processing of step **1212** is performed by a sound card which typically has the following

1 capabilities: (1) a sample rate selectable from about 4 K to 44 K; (2) a sample size of about 16
2 bits; (3) capable of analog to digital conversion; (4) capable of digital to analog conversion;
3 and (5) possesses IBM computer bus compatibility such as ISA, EISA, PCI, etc. In yet
4 another alternative embodiment the sound card used comprises a "Tahiti" multiple channel
5 Sound Card manufactured by Turtle Beach. Step **1230** allows for the intermediate output and
6 display of the desired signal following the signal conditioning and processing of step **1212**.
7 The display is accomplished by selection of a desired display mode and subsequent display on
8 the monitor **112**. The output of step **1212** is of a time series and is suitable for display
9 selection as in Figure 10a.

10 At step **1214**, the digitized and conditioned data is subjected to a sliding fast Fourier
11 transformation. The output of step **1214** is of time and frequency and is suitable for display
12 selection according to Figures 10b or 10c.

13 At step **1216**, time domain components of the data passes through a time domain
14 correlator and feature extraction process. In a similar fashion, in step **1218**, the frequency
15 domain components of the data passes through a frequency domain correlator and feature
16 extractor. In step **1220**, the outputs from the time domain correlator and feature extraction
17 process of step **1216** and the frequency domain correlator and feature extractor of step **1218**
18 are compared to a reference pattern and feature library, to determine whether the features
19 contained within the signal of interest match known disease modalities as recorded and
20 maintained within the reference pattern and feature library.

21 At step **1222**, the outputs from the time domain correlator and feature extraction
22 process of step **1216**, the frequency domain correlator and feature extractor process of step
23 **1218** and the results from the reference pattern and feature library comparison of step **1220**
24 are subjected to a recognition logic decision, where a determination is made as to whether a
25 disease or adverse condition is indicated. At step **1224**, the new disease modality indicated in
26 the recognition logic decision of step **1222** is then used to update the reference pattern and
27 feature library of step **1220**. In step **1226** a desired display mode such as depicted in Figures
28 10a, 10b and 10c is chosen for subsequent display on the monitor **112**. At step **1228** the
29 process is either terminated at step **1240** or begun anew at step **1202**.

30 The preceding descriptions of the operation of the present invention are merely
31 illustrative. In various embodiments of the disclosed invention operational steps may be

1 added, eliminated, performed in parallel or performed in a differing order.

3 METHOD

4
5 Sonospectrography can be used as a primary source of auscultatory information in a
6 routine physical examination or in population screening. Sonospectrography can be used in
7 cardiology and general medicine for the detection of functional and organic disorders of the
8 heart such as congenital defects, valve function, diseases of the pericardium and myocardium
9 and systemic and pulmonary hypertension. Sonospectrography can also be used as a
10 traditional stethoscope to capture sounds generated by other organs, such as the lungs,
11 trachea, larynx, liver and carotid arteries.

12 Elevated blood pressure has a number of causes. Regardless of the cause, however,
13 recent testing at the Uniformed Services University of Health Sciences shows that there is a
14 change in the frequency spectrum of both the aortic and pulmonary semilunar valve sounds
15 that is directly correlated to change in blood pressure of the associated systemic or pulmonary
16 circulatory system. This correlation was shown to be both measurable and repeatable in
17 testing on animals having systemic and pulmonary circulatory systems comparable to the
18 human system.

19 Elevated blood pressure increases back pressure at associated heart valves. This
20 increased back pressure results in more rapid closure of the heart valves and a resultant
21 audible "snap" of the valve leaflets. The acoustic signature that is associated with those heart
22 valve sounds has elevated frequency components as compared to the signature associated
23 with heart valves operating under normal blood pressures. As the blood pressure increases,
24 this frequency component also increases. It has been determined that this change in the
25 frequency component is transitory and returns to normal when the blood pressure returns to
26 normal.

27 Thus, where the sound emitted by the aortic semilunar valve is of an increased
28 frequency, this is indicative of higher systemic blood pressure. Similarly, where the sound
29 emitted by the pulmonary semilunar valve is of an increased frequency, this is indicative of
30 higher pulmonic blood pressure. Through the use of the apparatus of the present invention, it
31 is possible to detect and record sounds originating from the aortic and pulmonary semilunar

1 valves.

2 In practice, a sensor assembly is placed in contact with the patient. One side of the
3 sensor assembly contains an acoustic coupler that is placed in contact with the patient's skin
4 at the traditional auscultation point for the valve of interest, while a second acoustic coupler
5 on the opposite side faces away from the patient. This second acoustic coupler is designed to
6 acquire background sounds in synchronism with the acoustic coupler in contact with the
7 patient's skin to reject common mode signals reaching both couplers. While breathing
8 normally the sounds of the aortic and/or pulmonary semilunar valves are acquired,
9 preamplified and sent to a plurality of locations.

10 One analog signal is sent directly to an audio amplifier and high fidelity earphones. A
11 second analog signal is sent through a gain control potentiometer to an analog to digital
12 converter. The data is digitized and displayed in real time on a monitor. Visual feedback
13 from the monitor allows a precise setting of the gain control by the physician for the optimum
14 acquisition of data. In an alternative embodiment, an electronic strip chart is used in the
15 precise setting of the gain control. The physician adjusts gain control to maximize the
16 dynamic range of the captured signal.

17 In one embodiment, sounds are filtered normally. In an alternative embodiment,
18 sounds are filtered to de-emphasize interfering responses prior to being sent to the earphones
19 or the analog to digital converter. Data can be stored digitally, recalled for future analysis or
20 transmitted to another location.

21 Referring to Figure 12, data from recent in-vivo testing on animal subjects at the
22 Uniformed Services University of Health Sciences is shown. The subject had a pressure
23 catheter emplaced to provide actual pressure readings, and the present invention detected, and
24 processed the acoustic signature data from the second heart sounds. Figure 12 plots the
25 relationship between second heart sound A2 1302, and blood pressure 1304. As shown,
26 where there is a rise in the frequency of second heart sound 1302, there is a corresponding
27 rise in systolic pressure 1306, mean pressure 1308 and diastolic pressure 1310.

28 The subject whose pressure/frequency relationship is depicted in Figure 12, had a
29 resting systolic pressure of about 120 mm Hg, a resting diastolic pressure of about 77 mm Hg,
30 and a predominant second heart sound frequency of 28.5 Hz. The mean blood pressure was
31 thus about 90 mm Hg at 28.5 Hz. As the subject's blood pressure was artificially increased,

1 the associated frequency components of the second heart sound correspondingly increased.
2 Systolic pressure **1306** of the subject reached about 165 mm Hg, diastolic pressure **1310**
3 reached about 85 mm Hg, and frequency of second heart sound **1302** reached 36. Mean
4 pressure **1308** reached about 115 mm Hg. The slope of this mean pressure/frequency curve is
5 approximately 2 mm Hg per Hz. This pressure/frequency correlation was demonstrated in
6 each animal subject tested.

7 Across a population, measurement of the sound frequency associated with the closure
8 of the aortic and pulmonary semilunar valves will allow an estimate of the mean systemic and
9 pulmonary blood pressure. Specifically, using a range of pressure/frequency curves collected
10 from population samples, the present invention will allow an estimate of the mean systemic
11 and pulmonary pressure with a passive and non-invasive acoustic measurement of the
12 acoustic signature of the semilunar valve closure. As an example, if the mean pressure data
13 curve **1307** in Figure 12 presented an accumulated average from the population, then
14 measurement of a pulmonary semilunar valve closure sound frequency of 36 Hz **1309** would
15 provide an estimate that the mean pulmonic pressure was 115 mm Hg **1311**. In an otherwise
16 asymptomatic patient, this might provide sufficient clinical justification for use of an invasive
17 blood pressure catheter, with the attendant risk and cost, to confirm the pulmonic pressure.

18 Although the method of the present invention has been described in detail for purpose
19 of illustration, it is understood that such detail is solely for that purpose, and variations can be
20 made therein by those skilled in the art without departing from the spirit and scope of the
21 invention. The apparatus, operation and method of the present invention is defined by the
22 following claims.

1 **WHAT IS CLAIMED IS:**

- 2
- 3 1. An apparatus for monitoring blood pressure comprising:
- 4 a means for detecting audio signals;
- 5 a means for signal processing connected to the signal detecting means;
- 6 a means for signal storage connected to the signal processing means; and
- 7 a means for monitoring, connected to the signal processing means.
- 8 2. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
- 9 audio signal detecting means is a sensor assembly.
- 10 3. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
- 11 audio signal detecting means is a plurality of sensor assemblies.
- 12 4. An apparatus for monitoring blood pressure as claimed in claim 2, wherein the
- 13 sensor assembly comprises:
- 14 a housing having a front and a back;
- 15 an electronic module connected to the housing;
- 16 a shock dampener connected to the front of the housing;
- 17 a means for mounting connected to the housing;
- 18 a transducer connected to the mounting means;
- 19 an acoustic coupling connected to the transducer; and
- 20 a cover connected to the back of the housing.
- 21 5. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
- 22 housing further comprises a sound deadening material.
- 23 6. An apparatus for monitoring blood pressure as claimed in claim 5, wherein the
- 24 housing further comprises nickel plated aluminum.
- 25 7. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
- 26 housing further comprises:
- 27 a rim having an inside and an outside, located on the periphery of the front of the
- 28 housing;
- 29 a first indentation having an inside and an outside, that runs parallel and adjacent to
- 30 the inside of the rim;
- 31 a second indentation that runs parallel and adjacent to the inside of the first

1 indentation; and

2 a bore that is approximately centrally located within the second indentation.

3 8. An apparatus for monitoring blood pressure as claimed in claim 7, wherein the
4 electronic module nests within the bore.

5 9. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
6 shock dampener is an "O" ring.

7 10. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
8 mounting means is a plastic mounting ring.

9 11. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
10 transducer is a piezoelement.

11 12. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
12 acoustic coupling is a parametric acoustic transconductor.

13 13. An apparatus for monitoring blood pressure as claimed in claim 12, wherein
14 the parametric acoustic transconductor comprises latex foam.

15 14. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
16 signal processing means is a computer with a central processing unit.

17 15. An apparatus for monitoring blood pressure as claimed in claim 14, wherein
18 the computer with a central processing unit is an IBM compatible personal computer.

19 16. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
20 means for signal storage further comprises an array of disks.

21 17. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
22 means for signal storage further comprises an internal hard disk drive.

23 18. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
24 means for signal storage further comprises an internal hard disk drive.

25 19. An apparatus for monitoring blood pressure as claimed in claim 1, further
26 comprising:

27 a means for hard copy reproduction connected to the signal processing means.

28 20. An apparatus for monitoring blood pressure as claimed in claim 19, wherein
29 the means for hard copy reproduction further comprises a printer.

30 21. An apparatus for monitoring blood pressure as claimed in claim 1, further
31 comprising:

1 a means for remote connection connected to the signal processing means.

2 22. An apparatus for monitoring blood pressure as claimed in claim 21, wherein
3 the means for remote connection further comprises a modem.

4 23. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
5 means for monitoring further comprises a high resolution EGA color display monitor.

6 24. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
7 means for monitoring further comprises a high resolution VGA color display monitor.

8 25. An apparatus for monitoring blood pressure as claimed in claim 1, further
9 comprising:

10 a means for data acquisition connected to the signal detection means and the signal
11 processing means.

12 26. An apparatus for monitoring blood pressure as claimed in claim 25, wherein
13 the means for data acquisition comprises an amplifier.

14 27. An apparatus for monitoring blood pressure as claimed in claim 26, wherein
15 the amplifier comprises a tailored bandpass amplifier.

16 28. An apparatus for monitoring blood pressure as claimed in claim 27, wherein
17 the tailored bandpass amplifier comprises a low frequency response from a predetermined
18 first point to a predetermined second point, and a higher frequency response of a
19 predetermined level, from the predetermined second point to a predetermined third point.

20 29. An apparatus for monitoring blood pressure as claimed in claim 28, wherein
21 the predetermined level is about 20 dB.

22 30. An apparatus for monitoring blood pressure as claimed in claim 28, wherein
23 the predetermined first point is about 100 Hz, the predetermined second point is about 100 Hz
24 and the predetermined third point is about 600 Hz.

25 31. An apparatus for monitoring blood pressure as claimed in claim 28, where in
26 the predetermined second point is about 60 Hz.

27 32. A method of determining blood pressure comprising:

28 performing initialization procedures;

29 acquiring physiologic signals;

30 acquiring background signals;

31 subtracting background signals from physiologic signals creating physiologic data;

1 processing physiologic data forming a time domain output and a frequency domain
2 data output;

3 comparing the time domain output and the frequency domain output with a reference
4 pattern and feature library; and

5 determining if a disease modality is indicated.

6 33. A method of determining blood pressure as claimed in claim 32, wherein
7 performing initialization further comprises:

8 initializing system;

9 calibrating system;

10 selecting sensors;

11 inputting patient parameters; and

12 clearing buffers.

13 34. A method of determining blood pressure as claimed in claim 32, wherein
14 acquiring physiologic signals comprises acquiring acoustic signals.

15 35. A method of determining blood pressure as claimed in claim 32, wherein
16 acquiring physiologic signals comprises acquiring electric signals.

17 36. A method of determining blood pressure as claimed in claim 32, wherein the
18 physiologic signals are in an analog form, further comprising:

19 converting, the physiologic signals from the analog form to a digital form.

20 37. A method of determining blood pressure as claimed in claim 32, wherein the
21 background signals are in an analog form, further comprising the step:

22 converting the background signals from the analog form to a digital form.

23 38. A method of determining blood pressure as claimed in claim 32, wherein
24 processing further comprises:

25 applying signal conditioning and time domain averaging to the physiologic data
26 forming conditioned and averaged data;

27 formatting the conditioned and averaged data in an array creating formatted data;

28 aligning and normalizing formatted data, creating aligned and formalized data;

29 normalizing and integrating the aligned and formalized data, creating normalized and
30 integrated data, wherein said normalized and integrated data has time domain components

31 and frequency domain components;

1 passing the time domain components of the normalized and integrated data through a
2 time domain correlator and feature extraction process; and

3 passing the frequency domain components of the normalized and integrated data
4 through a frequency domain correlator and feature extractor, creating the time domain output
5 and the frequency domain output.

6 39. A method of determining blood pressure as claimed in claim 38, further
7 comprising:

8 displaying the formatted data on a monitor.

9 40. A method of determining blood pressure as claimed in claim 38, further
10 comprising:

11 displaying the aligned and normalized data on a monitor.

12 41. A method of determining blood pressure as claimed in claim 38, further
13 comprising:

14 displaying the normalized and integrated data on a monitor.

15 42. A method of determining blood pressure as claimed in claim 32, further
16 comprising:

17 updating the reference pattern and feature library.

18 43. A method of determining systemic blood pressure using sonospectrography
19 analysis comprising:

20 monitoring the frequency of a sound emitted by the aortic semilunar valve, wherein
21 the sound is detected using a sensor assembly, to monitor physiologic signals, the sensor
22 assembly comprising:

23 a housing having a front and a back;

24 an electronic module connected to the housing;

25 a shock dampener connected to the front of the housing;

26 a means for mounting connected to the housing;

27 an acoustic coupler connected to the mounting means;

28 a transducer connected to the acoustic coupler; and

29 a cover connected to the back of the housing;

30 processing the physiologic signals, the processing comprising:

31 applying signal conditioning and time domain averaging to the physiologic

1 signals to form conditioned and averaged data;
2 formatting the conditioned and averaged data in an array to create formatted
3 data;
4 aligning and normalizing formatted data, to create aligned and formalized data;
5 normalizing and integrating the aligned and formalized data, to create
6 normalized and integrated data that has time domain components and
7 frequency domain components;
8 passing the time domain components of the normalized and integrated data
9 through a time domain correlator and feature extraction process;
10 passing the frequency domain components of the normalized and integrated
11 data through a frequency domain correlator and feature extractor, to create a
12 time domain output and a frequency domain output;
13 comparing time domain output and the frequency domain output with a reference
14 pattern and feature library; and
15 determining if a disease modality is indicated.

16 44. A method of determining systemic blood pressure using sonospectrography
17 analysis as claimed in claim 43, further comprising:

18 acquiring background signals; and
19 subtracting background signals from physiologic signals.

20 45. A sensor assembly for detecting physiological sounds comprising:

21 a housing having a front and a back;
22 an electronic module connected to the housing;
23 a shock dampener connected to the front of the housing;
24 a means for mounting connected to the shock dampener;
25 an acoustic coupler connected to the mounting means;
26 a transducer connected to the acoustic coupler; and
27 a cover connected to the back of the housing.

28 46. A sensor assembly as claimed in claim 45, wherein the housing further
29 comprises a sound deadening material.

30 47. A sensor assembly as claimed in claim 46, wherein the housing further
31 comprises nickel plated aluminum.

1 48. A sensor assembly as claimed in claim 45, wherein the housing further
2 comprises:

3 a rim having an inside and an outside, that is located on the periphery of the front of
4 the housing;

5 a first indentation having an inside and an outside, that runs parallel and adjacent to
6 the inside of the rim;

7 a second indentation that runs parallel and adjacent to the inside of the first
8 indentation; and

9 a bore, that is approximately centrally located within the second indentation.

10 49. A sensor assembly as claimed in claim 48, wherein the electronic module nests
11 within the bore.

12 50. A sensor assembly as claimed in claim 45, wherein the shock dampener is an
13 "O" ring.

14 51. A sensor assembly as claimed in claim 45, wherein the mounting means is a
15 plastic mounting ring.

16 52. A sensor assembly as claimed in claim 45, wherein the transducer is a
17 piezoelement.

18 53. A sensor assembly as claimed in claim 52, wherein the acoustic coupling is a
19 parametric acoustic transconductor.

20 54. A sensor assembly as claimed in claim 53, wherein the parametric acoustic
21 transconductor comprises latex foam.

22 55. A sensor assembly for detecting physiological sounds comprising:

23 a housing, having a front, a back, and an interior;

24 an electronic module that nests in the interior of the housing;

25 a first shock dampener connected to the front of the housing;

26 a first mounting means connected to the first shock dampener;

27 a transducer connected to the first mounting means;

28 a first acoustic coupling connected to the transducer;

29 a second shock dampener connected to the back of the housing;

30 a second mounting means connected to the second shock dampener;

31 a second transducer connected to the second mounting means; and

1 a second acoustic coupling connected to the second transducer.

2 56. A sensor assembly as claimed in claim 55, wherein the housing further
3 comprises a sound deadening material.

4 57. A sensor assembly as claimed in claim 56, wherein the housing further
5 comprises nickel plated aluminum.

6 58. A sensor assembly as claimed in claim 55, wherein the housing further
7 comprises:

8 a first rim having an inside and an outside, that is located on the periphery of the front
9 of the housing;

10 a first indentation having an inside and an outside, that runs parallel and adjacent to
11 the inside of the first rim;

12 a second indentation that runs parallel and adjacent to the inside of the first
13 indentation;

14 a bore, that is approximately centrally located within the second indentation;

15 a second rim having an inside and an outside, that is located on the periphery of the
16 back of the housing;

17 a third indentation having an inside and an outside, that runs parallel and adjacent to
18 the inside of the second rim; and

19 a fourth indentation, that runs parallel and adjacent to the inside of the third
20 indentation.

21 59. A sensor assembly as claimed in claim 58, wherein the electronic module nests
22 within the bore.

23 60. A sensor assembly as claimed in claim 58, wherein the first shock dampener is
24 an "O" ring and the second shock dampener is an "O" ring.

25 61. A sensor assembly as claimed in claim 58, wherein the first mounting means is
26 a plastic mounting ring and the second mounting means is a plastic mounting ring.

27 62. A sensor assembly as claimed in claim 58, wherein the first transducer is a
28 piezoelement and the second transducer is a piezoelement.

29 63. A sensor assembly as claimed in claim 58, wherein the first acoustic coupling
30 is a parametric acoustic transducer and the second acoustic coupling is a parametric
31 acoustic transducer.

1 64. A sensor assembly as claimed in claim 58, wherein the parametric acoustic
2 transducer comprises latex foam.

3 65. An apparatus for determining blood pressure comprising:
4 an acoustic coupling, wherein the acoustic coupling provides a low-loss acoustic
5 transmission coupling between skin and a piezoelectric transducer.

6 66. An apparatus for determining blood pressure as claimed in claim 65, wherein
7 the acoustic coupling is a parametric acoustic transducer.

8 67. An apparatus for determining blood pressure as claimed in claim 65, wherein
9 the acoustic coupling has a high conduction coefficient.

10 68. An apparatus for determining blood pressure as claimed in claim 65 wherein
11 the acoustic coupling comprises latex foam.

12 69. An apparatus for monitoring blood pressure comprising:

13 an acoustic coupling;

14 a transducer connected to the acoustic coupling;

15 an electronic module connected to the transducer;

16 a data acquisition module connected to the electronic module; and

17 a data cable connected to the electronic module and the data acquisition module.

18 70. An apparatus for monitoring blood pressure as claimed in claim 69, wherein
19 the data cable is a twisted shielded pair.

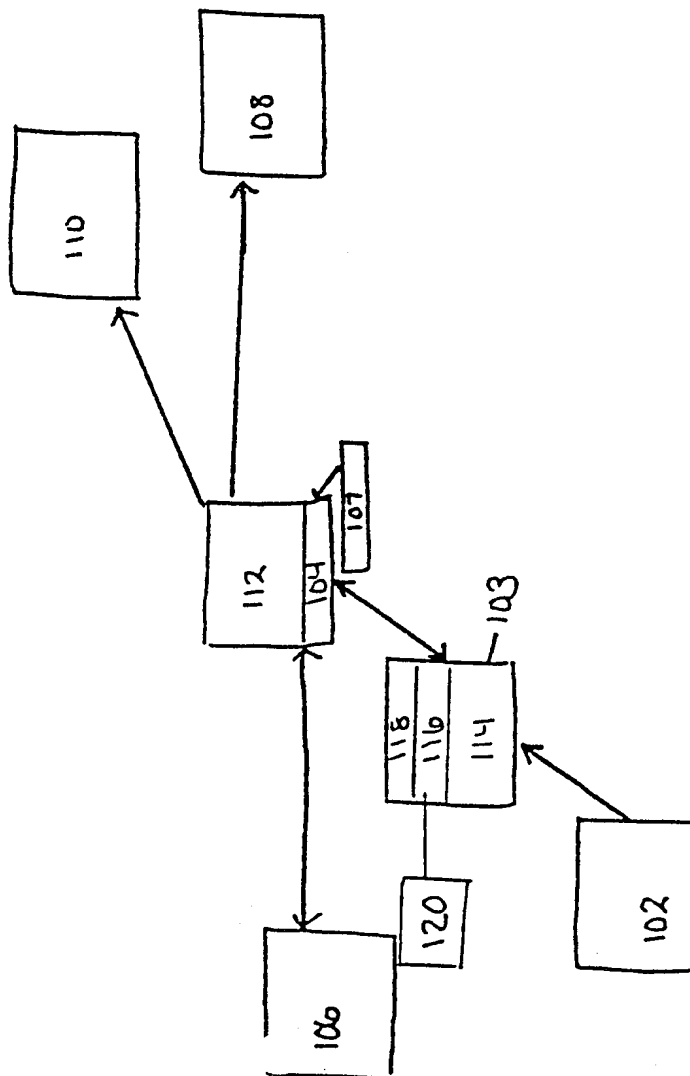


Fig. 1

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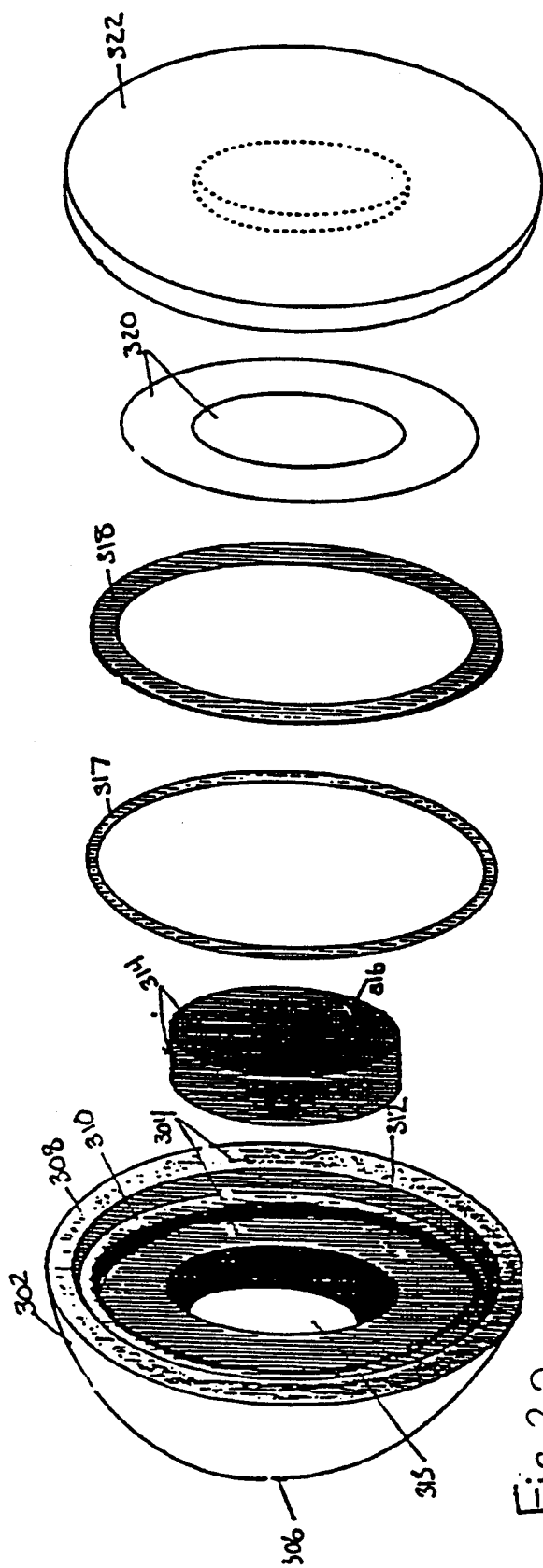


Fig. 2a

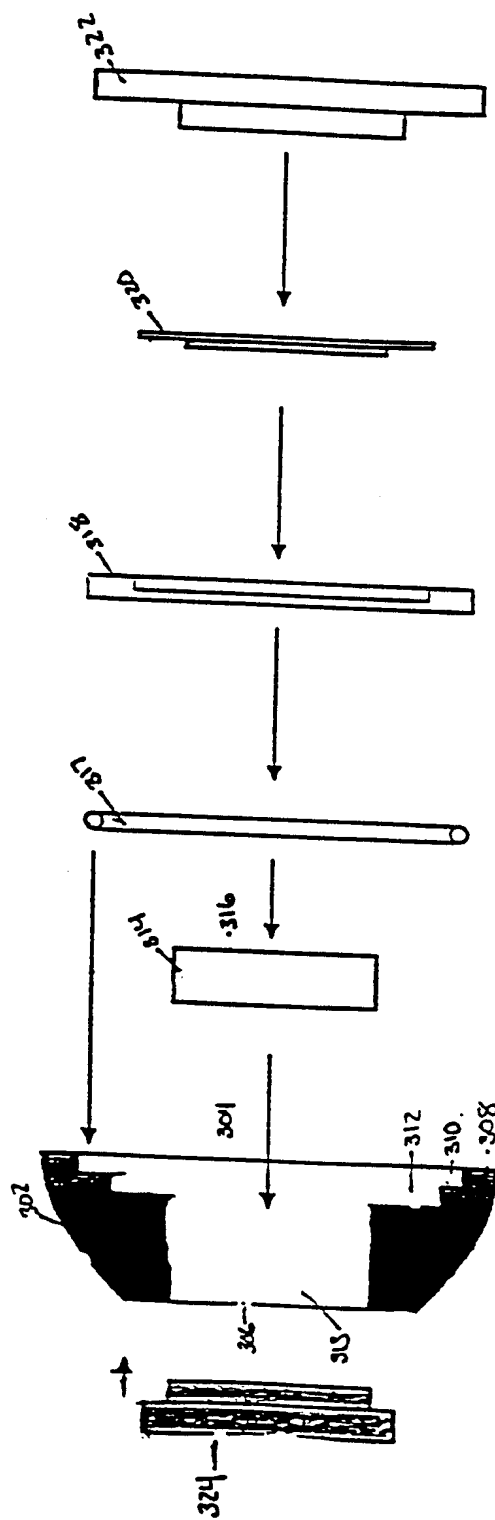


Fig 2b

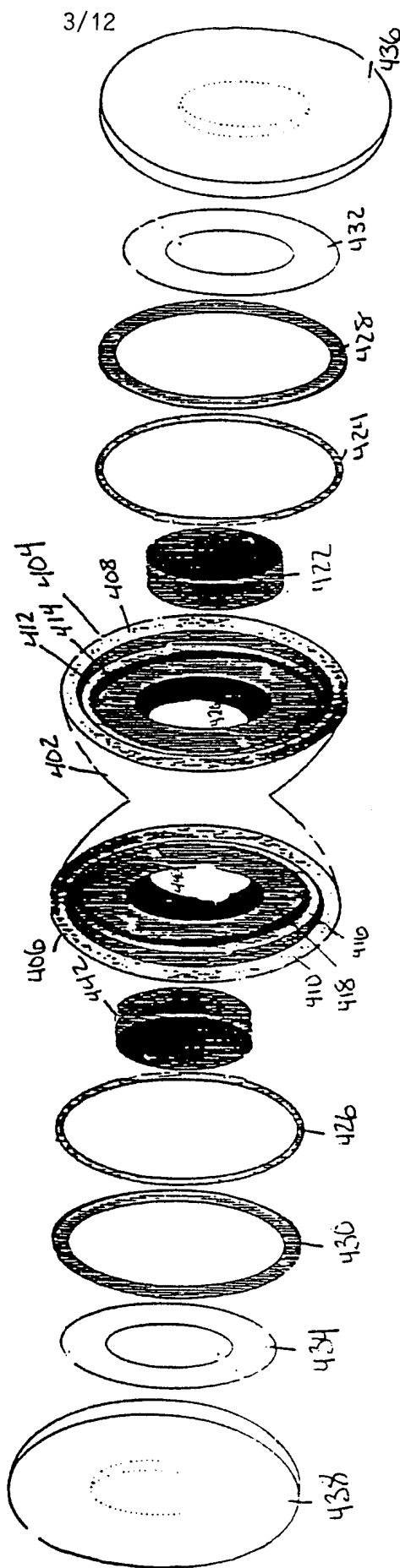


Fig. 3

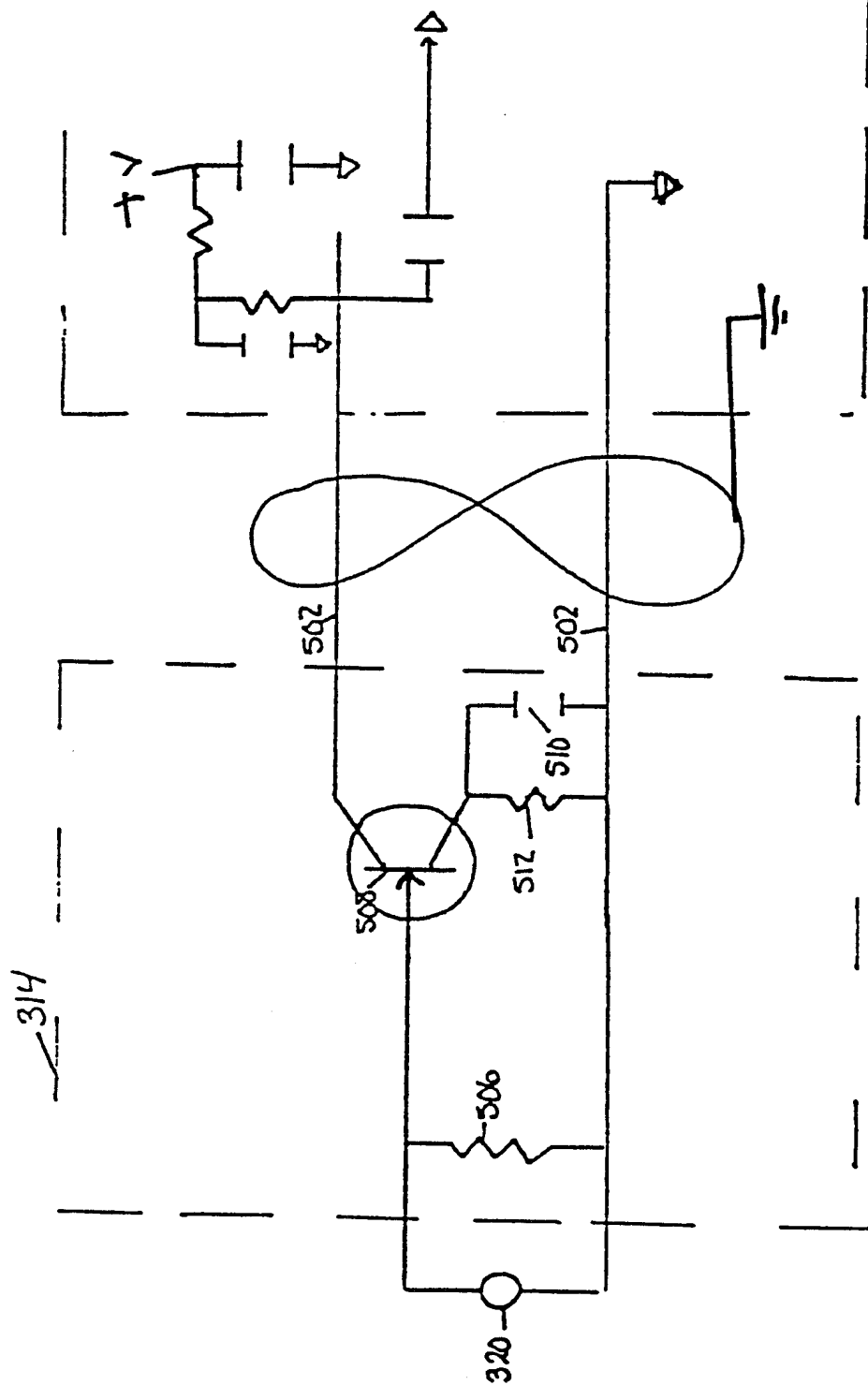


Fig. 4

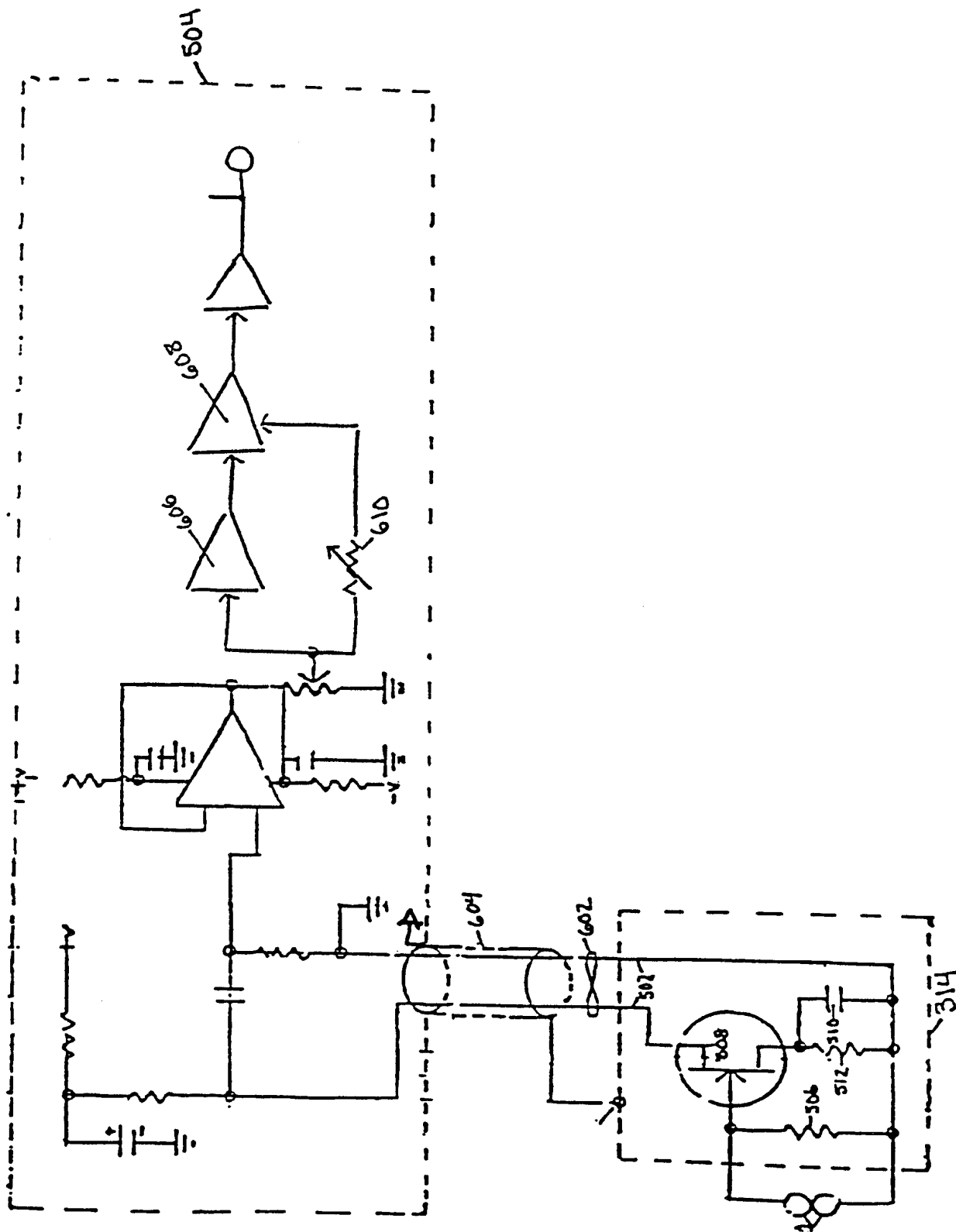


Fig. 5

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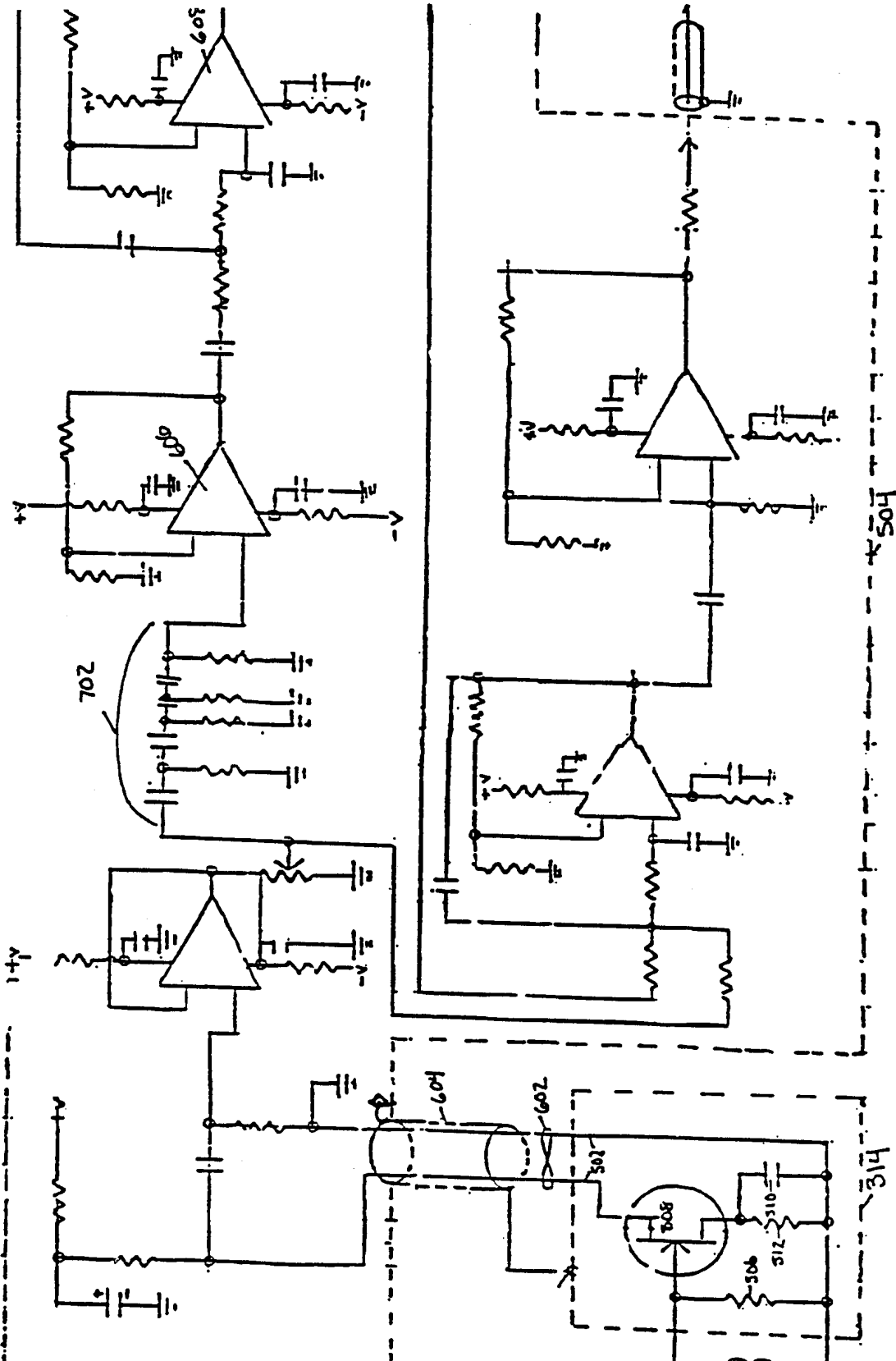


Fig. 6

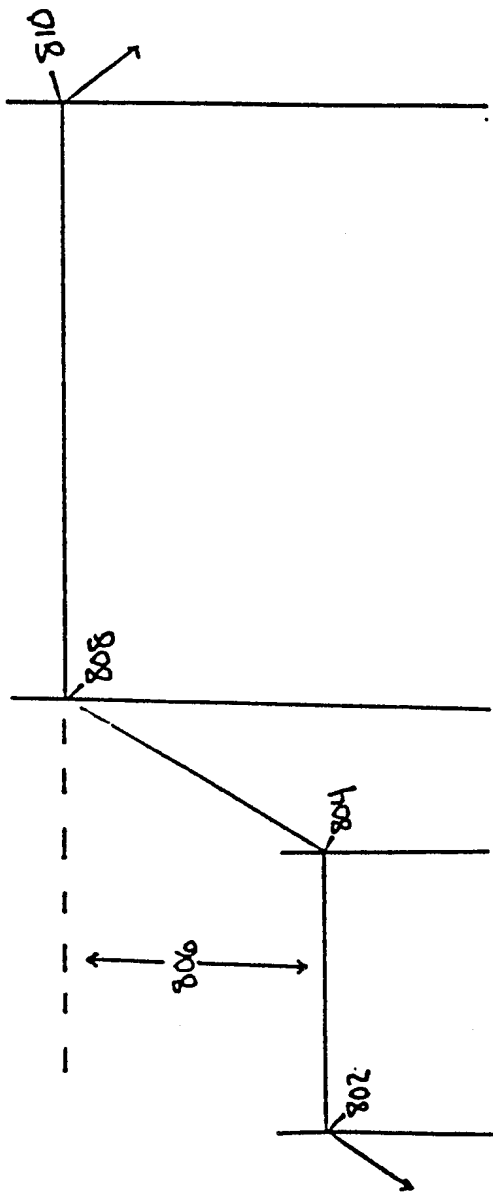


Fig. 7

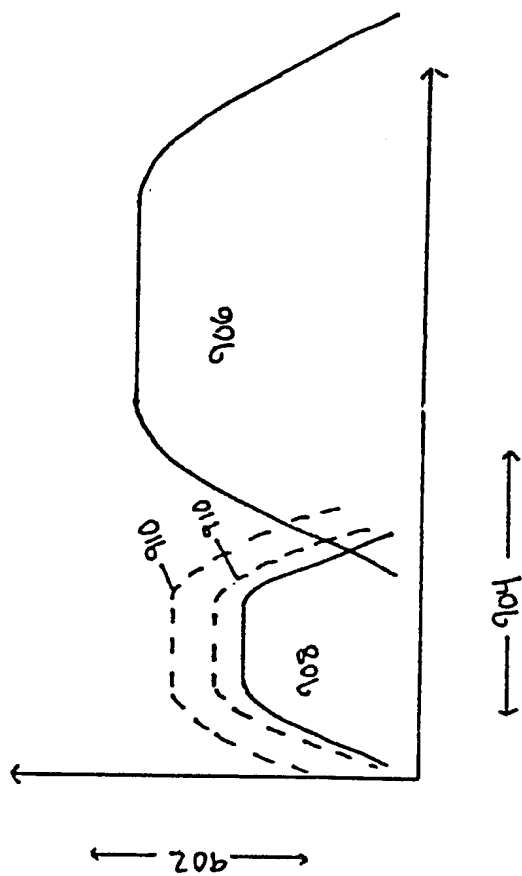


Fig. 8

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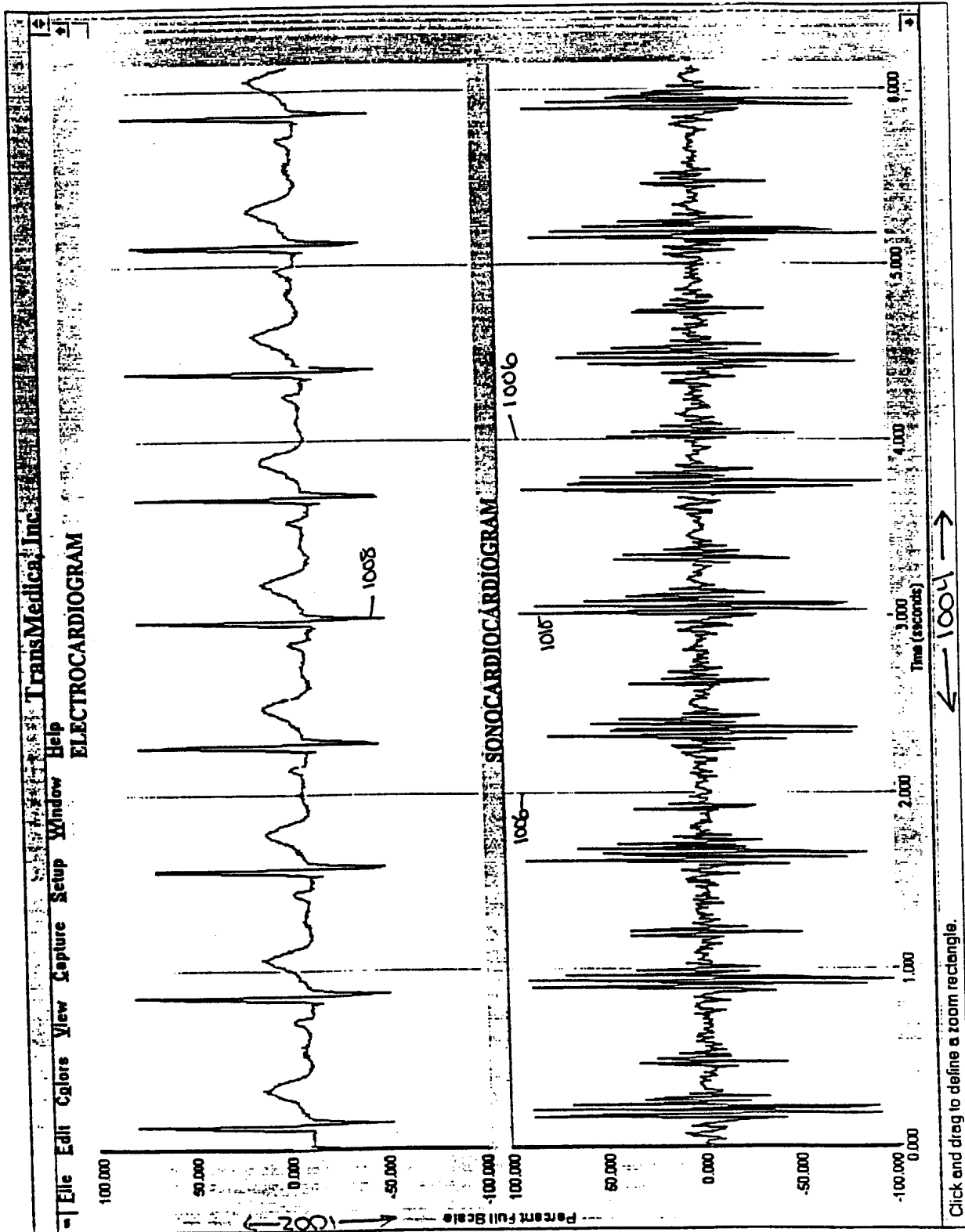


Fig. 9

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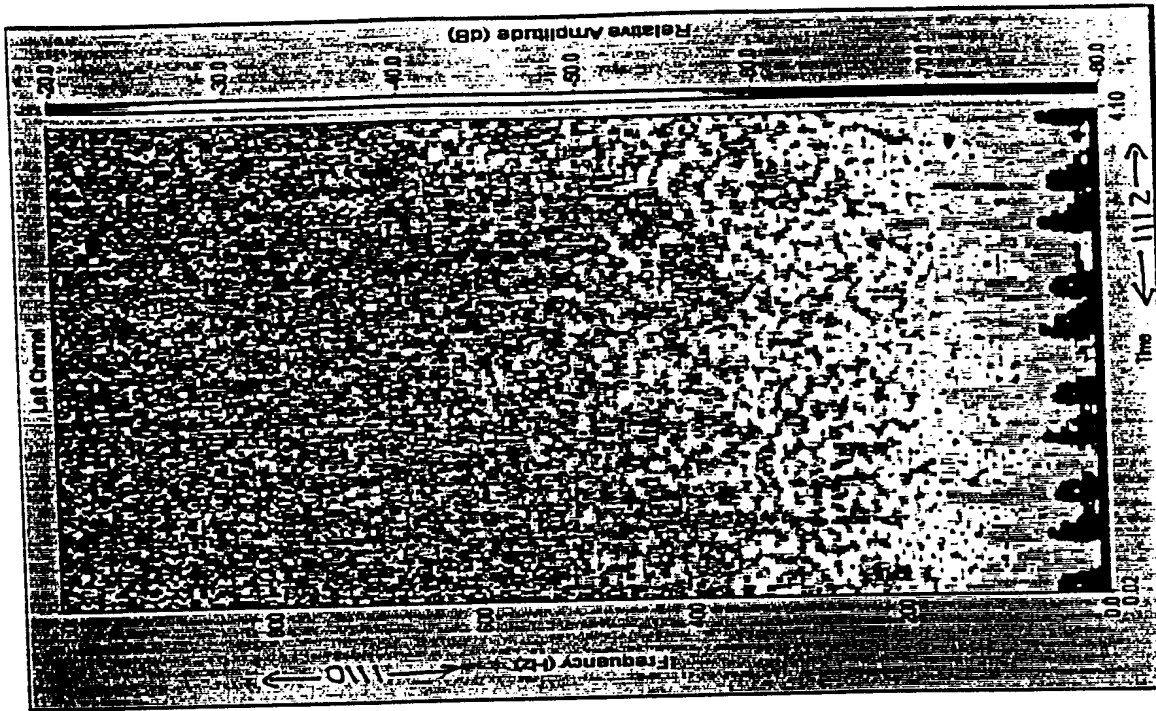


Fig. 10c

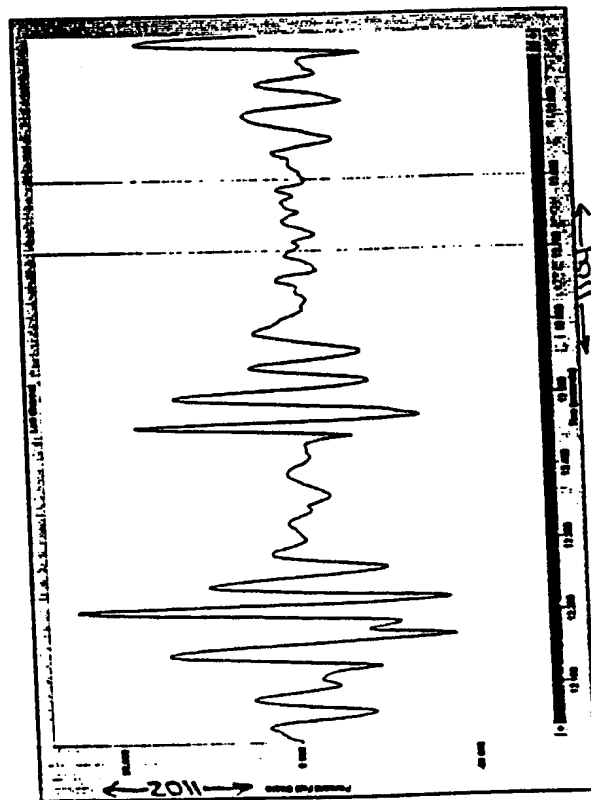


Fig. 10a

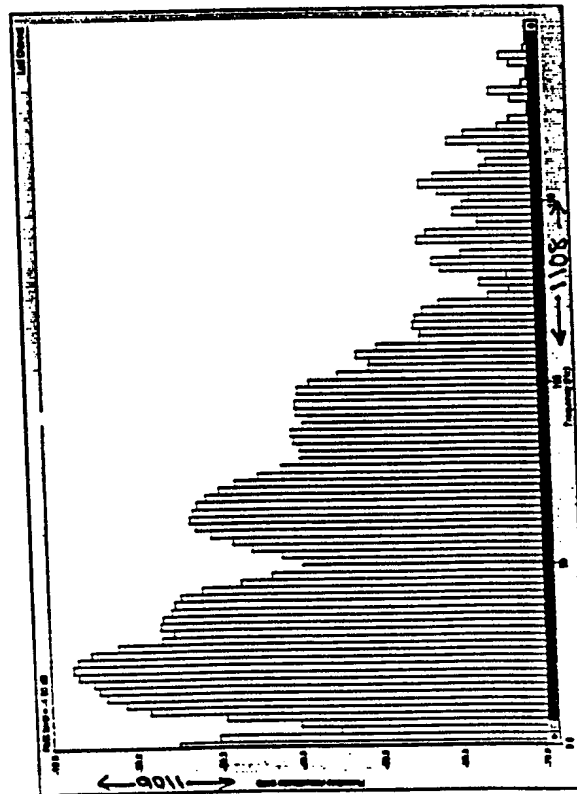
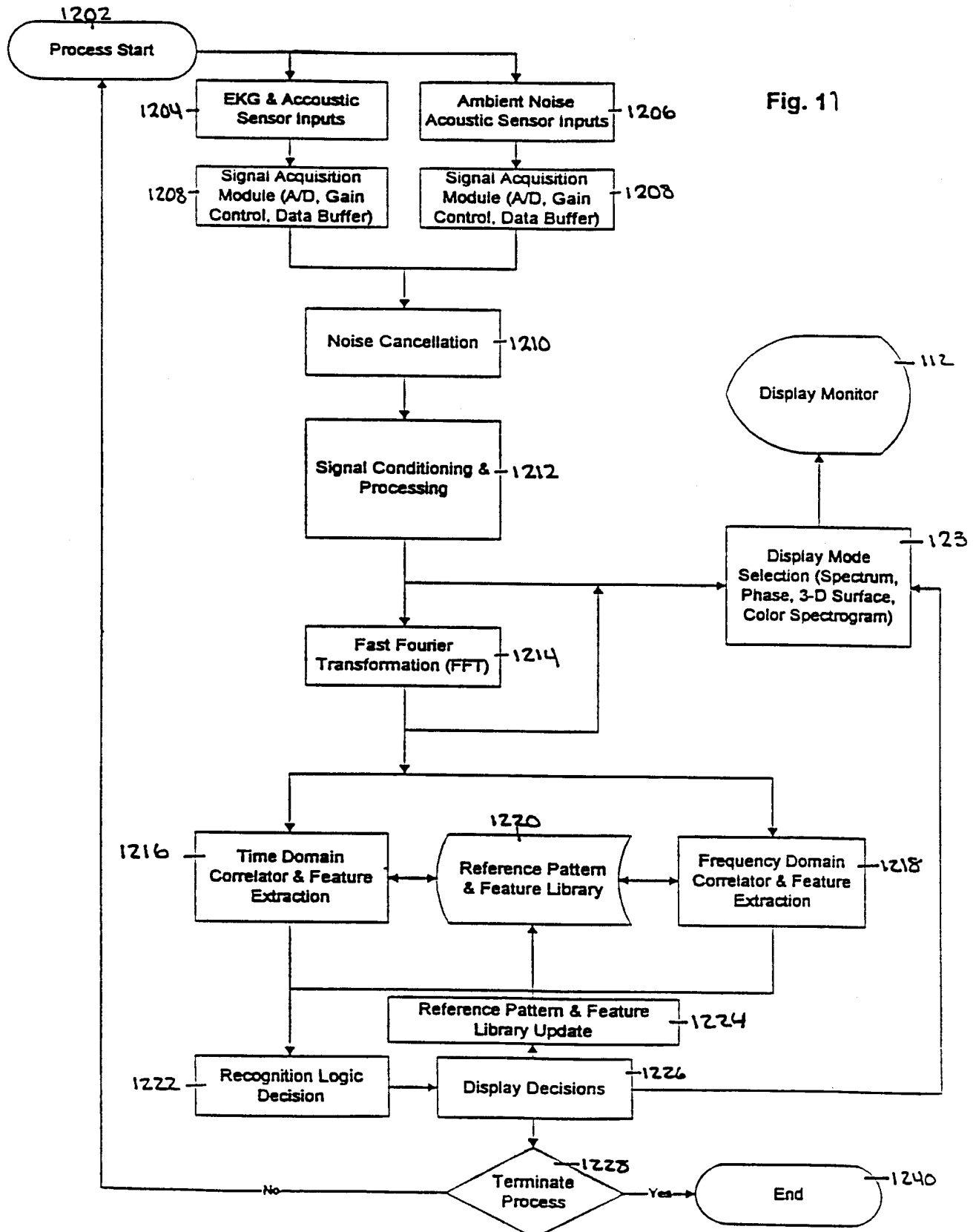


Fig. 10b

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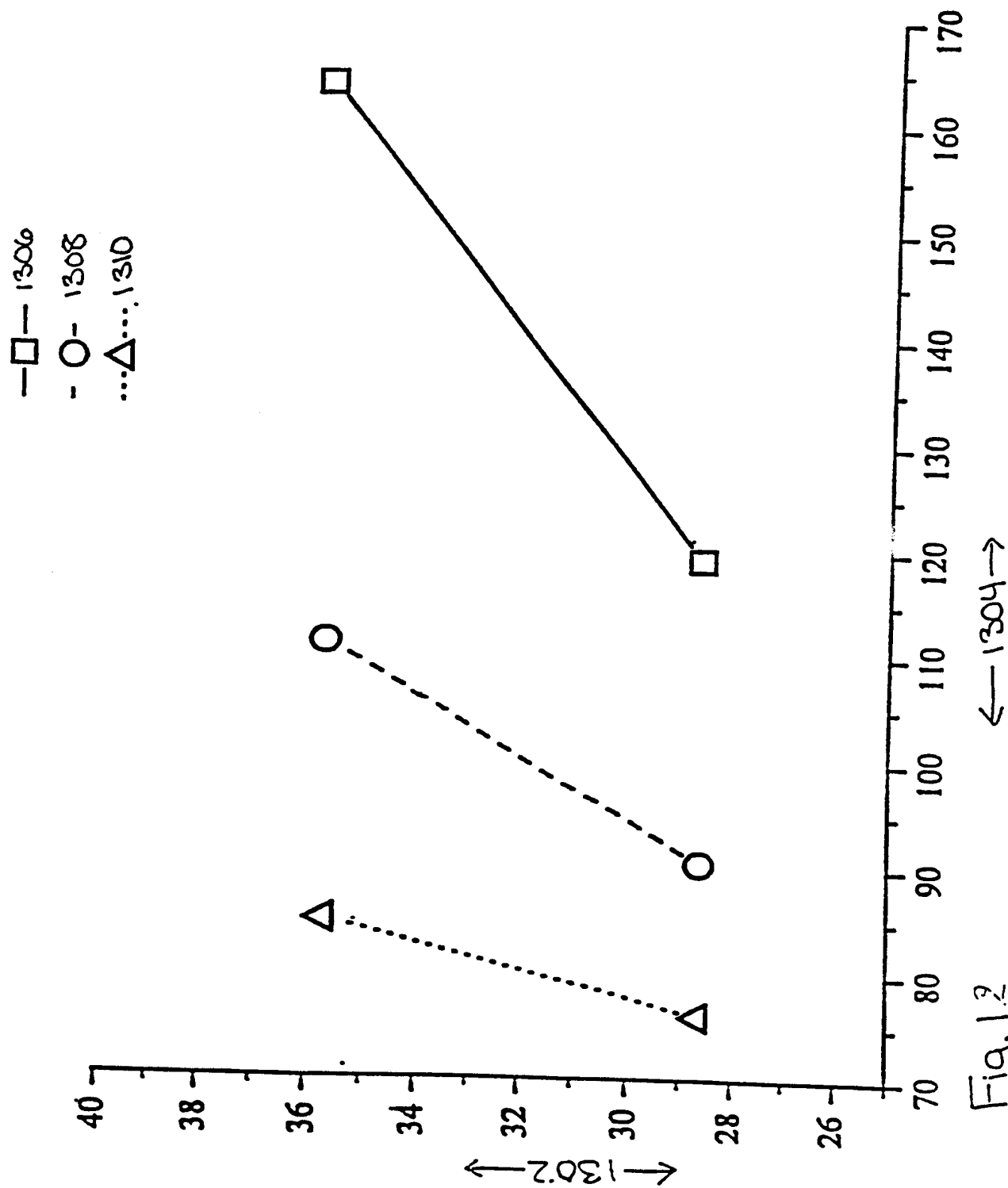


Fig. 12

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/21917

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B7/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 020 110 A (W.J. KASPARI) 10 December 1980	1-4, 7, 9-11, 14, 25, 26, 32, 34-37, 39, 43-45, 48, 50-52, 60-62, 65, 69 6, 47, 55 57, 58
A	see page 3, line 4 - line 37	
A	see page 7, line 11 - page 9, line 18	
	see page 12, line 24 - page 17, line 17 --- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

7 April 1998

Date of mailing of the international search report

17/04/1998

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/21917

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 467 775 A (T.F. CALLAHAN ET AL.) 21 November 1995	1-3,5, 10,14, 21, 25-28, 44-46, 48,51, 55,56,69
A	see column 4, line 41 - column 5, line 17	32-37
A	see column 6, line 5 - column 7, line 28	43,58
A	see column 8, line 5 - line 44 see column 11, line 56 - column 12, line 55	65,67
A	US 4 967 760 A (W.R. BENNETT, JR. ET AL.) 6 November 1990 cited in the application	1-5,14, 19,20
A	see column 1, line 25 - line 53	25-28
A	see column 4, line 1 - line 63	32-36,39
A	see column 9, line 9 - column 10, line 45	40,43-46
A	see column 10, line 66 - column 11, line 24 see column 13, line 64 - column 15, line 31	55,56, 65,67,69
A	US 5 025 809 A (K.H. JOHNSON ET AL.) 25 June 1991	1,14,25, 32,34-36
A	see column 6, line 19 - column 9, line 20	38-43
A	US 5 205 295 A (B. DEL MAR ET AL.) 27 April 1993	1,14, 16-20, 25,35
A	see column 9, line 46 - column 11, line 44	36,38-42

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/21917

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 5025809 A	25-06-91	NONE	
US 5205295 A	27-04-93	WO 9404075 A	03-03-94



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ :
A61B 7/04

A1

(11) International Publication Number: WO 98/26716

(43) International Publication Date: 25 June 1998 (25.06.98)

(21) International Application Number: PCT/US97/21917

(22) International Filing Date: 2 December 1997 (02.12.97)

(30) Priority Data:
08/769,156 18 December 1996 (18.12.96) US(71)(72) Applicant and Inventor: MOHLER, Sailor [US/US]; 5410
Lightening View, Columbia, MD 21045 (US).(74) Agent: ROBERTS, Jon, L.; Roberts & Brownell, L.L.C., Suite
212, 8381 Old Courthouse Road, Vienna, VA 22182 (US).(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR,
BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE,
GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,
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TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH,
KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ,
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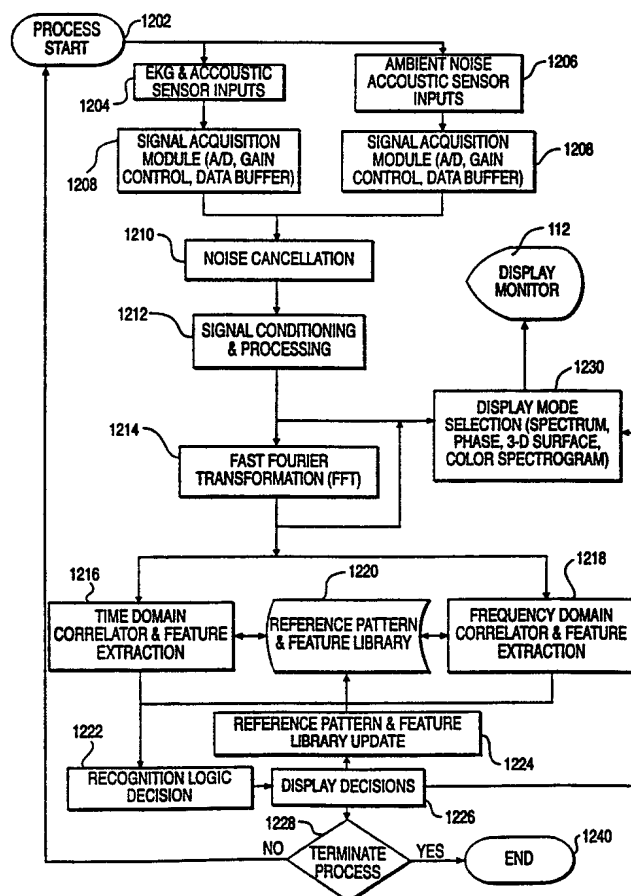
With international search report.

Before the expiration of the time limit for amending the
claims and to be republished in the event of the receipt of
amendments.

(54) Title: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENT

(57) Abstract

An apparatus detection of the second heart sound acoustic signature associated with heart valve closure includes a sensor assembly (102) comprising a housing (302; 402), an electronic module (314; 422), a shock dampener (316; 432; 434), a mounting means, a transducer (320; 432; 434), an acoustic coupling (322; 436; 438) and a back cover. The sensor assembly (102) is connected to a data acquisition module (103) which in turn is connected to a signal processing means (104), a remote connection means (110) and a monitor (112). An improved acoustic coupling (322; 436; 438) is disclosed that provides low-loss acoustic transmission between the skin of the patient and the sensor assembly (102).



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TITLE: PIEZOELECTRIC SENSOR FOR BLOOD PRESSURE MEASUREMENTFIELD OF THE INVENTION

This invention relates generally to an apparatus, operation and method for measurement of blood pressure. In particular, this invention relates to an apparatus, operation and method for the detection, identification and characterization of sounds relating to either systemic or pulmonary blood pressure through the use of sonospectrography.

BACKGROUND OF THE INVENTION

Blood pressure is the force exerted by the blood against the inner walls of blood vessels. Blood pressure determination is an important diagnostic tool. The blood vessels that comprise the vascular system can be grouped into two main divisions, a systemic circuit and a pulmonary circuit. In the systemic circuit, high blood pressure may indicate the presence of arteriosclerosis or other vascular disease, while low blood pressure may indicate shock or blood loss. Detection and measurement of elevated pulmonary blood pressure is a key diagnostic indicator for a number of pulmonary diseases, such as: cystic fibrosis, pleuresy, lung pulmonary diseases, and pulmonary impedance. Early diagnosis of these diseases greatly assists in symptom mitigation and improved patient quality of life.

The systemic circuit includes the aorta and its branches that deliver oxygenated blood to all body tissues, as well as the companion system of veins returning blood to the right atrium. Freshly oxygenated blood received by the left atrium is forced into the systemic circuit by the contraction of the left ventricle. When the left ventricle contracts, the mitral valve closes, and the only exit is through the aortic valve into the aorta.

The peripheral nature of certain systemic circuit arteries in the body extremities allows for the traditional indirect measurement of the systolic and diastolic pressures with a sphygmomanometer blood pressure cuff. While this method is effective for many patients, use of the traditional blood pressure cuff on an extremity may be contraindicated for patients suffering from any number of problems including severe extremity trauma, or burns. In patients where use of the traditional blood pressure cuff is contraindicated, there is no reliable alternative method of

1 monitoring blood pressure. This is extremely important in trauma patients where prompt
2 detection of blood pressure changes are needed to counteract the effects of shock or large blood
3 loss.

4 The pulmonic circuit provides for blood circulation from the right ventricle through the
5 pulmonary valve into the pulmonary artery. The pulmonary artery extends upward and
6 posteriorly from the heart, dividing into right and left branches which serve the right and left
7 lungs, respectively. Within the lungs the right and left branches of the pulmonary artery divide
8 repeatedly giving rise to arterioles that continue into the capillary networks associated with the
9 walls of the alveoli. Gas exchange occurs as the blood moves through these capillaries, so that
10 when the blood enters the venules of the pulmonary circuit, it is well oxygenated and poor in
11 carbon dioxide. The pulmonary venules merge forming small veins, which in turn converge
12 forming larger veins. Four pulmonary veins return oxygenated blood to the left atrium, thereby
13 completing the pulmonic circuit.

14 None of the arteries of the pulmonic system are located in extremities and therefore
15 measurement of pulmonic system pressure with a blood pressure cuff is not possible.

16 At present, the only reliable method for measuring pulmonic system blood pressure is
17 through use of an invasive blood pressure catheter that is inserted directly into the pulmonary
18 artery. This diagnostic procedure has a substantial degree of risk and is expensive, its use is thus
19 generally seen as an unjustified procedure in patients without other symptoms.

20 The physician may attempt to detect and differentiate the abnormal sounds that occur
21 with elevated blood pressure using traditional auscultation. Closure of the aortic and pulmonary
22 semilunar heart valves generate a sound component that is in the audio frequency range. As the
23 systemic or pulmonic blood pressure increases, the frequency components of the related heart
24 valve also increase. This increased frequency audio component is not present in a healthy
25 patient. However, aural detection of this frequency increase is extremely difficult because the
26 physician must determine the absolute frequency of the audio component of the heart valve of
27 interest. Additionally, the sounds are very weak and heavily contaminated with noise from other
28 patient heart sounds, other normal patient body sounds and external ambient noise in the room.
29 Further, the audio component of the aortic and pulmonary semilunar heart valves are heavily
30 attenuated as they pass through the patient's chest and chest wall.

31 A need exists for a non-invasive, low cost and reliable means for determining systemic

1 blood pressure in those situations where traditional means are contraindicated. A need also
2 exists for a non-invasive, low cost and reliable means for determining pulmonary blood pressure.

3 4 DESCRIPTION OF RELATED ART

5
6 As mentioned, the sounds related to systemic and pulmonary heart pressure are difficult
7 to discern. United States Patent No. 4,528,690 to Sedgwick; United States Patent No. 3,790,712
8 to Andries; and United States Patent No. 3,160,708 to Andries et al. disclose relatively simple
9 electronic stethoscopes as methods for amplification of the sounds in an attempt to raise the sub-
10 audible components into the audible range. However, simple amplification of the entire
11 frequency spectrum, as disclosed, does not help in determining the absolute frequency of the
12 heart valve sounds, or in detecting the subtle changes of this frequency that occur with changes in
13 blood pressure.

14 To this end, United States Patent No. 4,594,731 to Lewkowicz and United States Patent
15 No. 5,347,583 to Dieken et al. disclose various forms of selective filtering or signal processing
16 on the audio signal in the electronic stethoscope. Lewkowicz discloses a means for shifting the
17 entire detected spectrum of sounds upward while expanding the bandwidth so that they are more
18 easily perceived by the listener. Dieken et al. discloses an electronic stethoscope having a greater
19 volume of acoustic space and thereby improving low frequency response.

20 The electronic stethoscope provides a moderate improvement over conventional methods
21 of auscultation. However, information remains in audio form only and is transient; the physician
22 is unable to visualize the data and either freeze the display or focus on a particular element of the
23 signal retrieved. To accommodate that deficiency, the technique of phonocardiography, which is
24 the mechanical or electronic registration of heart sounds with graphic display, is used. United
25 States Patent No. 5,218,969 to Bredesen et al.; United States Patent No. 5,213,108 to Bredesen
26 et al.; United States Patent No. 5,012,815 to Bennett, Jr. et al.; United States Patent No.
27 4,967,760 to Bennett, Jr. et al.; United States Patent No. 4,991,581 to Andries; and United States
28 Patent No. 4,679,570 to Lund et al. disclose phonocardiography with signal processing and
29 visual/audio output. United States Patent No. 5,301,679 to Taylor; and United States Patent No.
30 4,792,145 to Eisenberg et al. disclose phonocardiography with signal processing and visual
31 display.

1 The process of phonocardiography as commonly known in the art, acquires acoustic data
2 through an air conduction microphone strapped to a patients chest, and provides the physician
3 with a strip chart recording of this acoustic data. The strip chart is generally created at a rate of
4 100 mm/second. As this method is generally used, with the exception of the created strip chart,
5 data is not stored. Thus, it is not possible to manipulate and/or process the data post acquisition.
6 In addition, phonocardiography does not provide the sensitivity needed to monitor softer
7 physiological sounds such as the closure of the semilunar valves and blood flow through the
8 circulatory system.

9 As previously noted, one problem in traditional auscultation is ambient noise from the
10 room in which the examination is occurring, which reduces the signal-to-noise ratio of the
11 sounds of interest. United States Patent No. 4,672,977 to Kroll discloses a method for automatic
12 lung sound cancellation and provides visual and audio output. United States Patent No.
13 5,309,922 to Schecter et al. discloses a method for cancellation of ambient noise to enhance
14 respiratory sounds and provides visual and audio output. United States Patent No. 5,492,129 to
15 Greenberger discloses a method for reducing general ambient noise and provides audio output.

16 United States Patent No. 5,036,857 to Semmlow et al. discloses a method of
17 phonocardiography with piezoelectric transducer. Semmlow specifically recommends against
18 Fast Fourier Transformation analysis of the phonocardiography data and relies on processing by
19 other means. United States Patent No. 5,109,863 to Semmlow et al.; and United States Patent
20 No. 5,035,247 issued to Heimann also disclose piezoelectric transducers.

21 United States Patent No. 5,002,060 to Nedivi, discloses both heart and respiratory
22 sensors, with Fast Fourier Transformation analysis. In the technique disclosed by Nedivi the
23 sensors are not physically attached to the patient. Thus the sensors are not capable of detecting
24 the low intensity sound of the aortic and pulmonary semilunar heart valves.

25 Devices currently known in the art do not provide either a means of determining systemic
26 blood pressure where use of a blood pressure cuff is contraindicated, or a low risk, non-invasive
27 means of determining pulmonic blood pressure. Additionally, the related art does not provide the
28 level of aural sensitivity needed to reliably detect the sounds of the aortic and pulmonary
29 semilunar heart valves and determine the precise frequency of these sounds.

30 What is needed is a safe, sensitive and noninvasive means of measuring systemic and/or
31 pulmonic blood pressure. This is accomplished through the present invention. Through the use

1 of sonospectrography, a procedure based on integral spectral analysis techniques, systemic
2 pressure can be monitored in conditions where traditional auscultation is contraindicated.
3 Additionally, sonospectrography can be used to monitor pulmonic pressure in an inexpensive,
4 noninvasive and low risk manner, allowing for the early detection of conditions such as cystic
5 fibrosis, pleuresy, lung pulmonary diseases and pulmonary impedance. Sonospectrography is
6 defined as the separation and arrangement of the frequency components of acoustic signals in
7 terms of energy or time.

8 Further embodiments of the present invention provide a means of detecting physiological
9 sounds, such as sounds emitted by the heart and other body organs as well as sounds related to
10 the flow of blood through the circulatory system. Analysis of these sounds can be used to
11 determine systemic and pulmonary blood pressure, monitor anesthesiology, determine cardiac
12 output, monitor the circulation of diabetic individuals, and monitor fetal heartbeat as well as
13 detect conditions such as aneurysms, arterial occlusions, arthritic decrepitation, phlebitis, venous
14 thrombosis, intravascular blood clotting and carotid artery disease.

15 16 SUMMARY OF THE INVENTION

17
18 It is therefore an object of the present invention to provide an apparatus, operation and
19 method for the detection and analysis of physiological sounds, such as sounds emitted by the
20 heart and other body organs as well as sounds related to the flow of blood through the circulatory
21 system.

22 It is a further object of the present invention to provide an apparatus, operation and
23 method to be used to determine systemic and pulmonary blood pressure, monitor anesthesiology,
24 determine cardiac output, monitor the circulation of diabetic individuals, and monitor fetal
25 heartbeat as well as detect conditions such as aneurysms, arterial occlusions, arthritic
26 decrepitation, phlebitis, venous thrombosis, intravascular clotting and carotid artery disease.

27 It is a further object of the present invention to provide this apparatus, operation and
28 method through the use of sonospectrography.

29 It is a further object of the present invention to provide this apparatus, operation and
30 method through a synchronized and coordinated combination of sonospectrography and
31 electrocardiogram signals.

1 It is a further object of the present invention to provide this apparatus, operation and
2 method through visual display means that provide insight to the subtle characteristics of the
3 acoustic signature.

4 It is a further object of the present invention to provide this apparatus, operation and
5 method through selective time and frequency windowing of the acoustic signals.

6 It is a further object of the present invention to provide this apparatus, operation and
7 method through real-time signal processing or recorded-signal post processing.

8 It is a further object of the present invention to provide this apparatus, operation and
9 method through use of single or multiple transducers.

10 It is a further object of the present invention to provide this apparatus, operation and
11 method through a computer assisted search algorithm to identify optimal placement of the
12 transducer(s) on the patient's chest wall.

13 It is a further object of the present invention to provide this apparatus, operation and
14 method in office environments with moderate to high ambient noise levels, through adaptive
15 noise cancellation techniques.

16 It is a further object of the present invention to provide this apparatus, operation and
17 method in a form that provides for dynamic template building to facilitate disease detection and
18 identification.

19 It is a further object of the present invention to provide this apparatus, operation and
20 method through neural network techniques.

21 It is a further object of the present invention to provide an acoustic coupling that
22 minimizes signal loss between the subject-detector interface and allows for the detection of
23 sounds heretofore undetectable in a normal room environment.

24 It is a further object of the present invention to extend the ability of clinicians to analyze
25 sounds which are lower in amplitude than those detectable by the unaided ear.

26 It is a further object of the present invention to extend the ability of clinicians to analyze
27 sounds which are lower in frequency than those detectable by typical auscultation techniques.

28 It is a further object of the present invention to increase detection of a specified frequency
29 range through the use of a tailored bandpass amplifier.

30 It is a further object of the present invention to provide a means for data storage, data
31 manipulation and data transmission.

1 It is a further object of the present invention to provide this apparatus, operation and
2 method through advanced processing of acoustic signatures in the time and frequency domain to
3 isolate and display the sound components associated with pulmonary and/or aortic heart valve
4 closure.

5 It is a further object of the present invention to provide an apparatus, operation and
6 method that is suitable for routine physical examination screening and early diagnosis of elevated
7 pulmonic blood pressure thereby providing an opportunity for early intervention to enhance the
8 patient's productive life.

9 It is a further object of the present invention to provide an apparatus, operation and
10 method that is suitable for monitoring of systemic blood pressure in patients where use of a
11 traditional blood pressure cuff is contraindicated.

12 These and other objects of the present invention will become obvious to those skilled in
13 the art upon review of the following disclosure.

14 An apparatus for determining blood pressure in accordance with the present invention
15 includes a sensor assembly comprising a housing, an electronic module, a shock dampener, a
16 mounting means, a piezoelectric transducer, an acoustic coupling and a back cover. The sensor
17 assembly is connected to a data acquisition module which in turn is connected to a signal
18 processing means. The signal processing means is connected to an electronic storage means, a
19 hard copy reproduction means, a remote connection means and a monitor. In an alternative
20 embodiment of the invention a plurality of sensor assemblies are connected to the data
21 acquisition module. In another alternative embodiment of the invention a means for determining
22 an electrocardiogram is connected to the signal processing means. In yet another alternative
23 embodiment of the invention, data acquisition module is connected to high-fidelity earphones.

24 The operation for determining blood pressure in accordance with the present invention
25 includes:

- 26 1) performing start-up procedures;
- 27 2) acquiring physiologic signals;
- 28 3) acquiring ambient or background signals;
- 29 4) processing and subtracting ambient signals from physiologic signals;
- 30 5) conditioning and processing resultant data;
- 31 6) subjecting the conditioned and processed data to Fast Fourier Transformation;

- 7) passing the time domain components of the data through a time domain correlator and feature extraction process;
- 8) passing the frequency domain components of the data through a frequency domain correlator and feature extraction process;
- 9) comparing the time domain output and the frequency domain output to a reference pattern and feature library;
- 10) determining whether the time domain output and frequency domain output match known disease modalities;
- 11) determining whether a disease modality is indicated;
- 12) updating the reference pattern and feature library; and
- 13) providing the information regarding the disease modality to the physician so that a treatment regimen may commence.

The method for determining blood pressure in accordance with the present invention includes monitoring the sounds of the aortic and/or the pulmonary semilunar valves. Where one wishes to determine systemic pressure, the aortic semilunar valve is monitored. This is done by placing the acoustic coupling of the sensor assembly adjacent to the patient's skin at the traditional auscultation point for the aortic valve. Where one wishes to monitor pulmonary pressure, the pulmonary semilunar valve is monitored. This is done by placing the acoustic coupling of the sensor assembly in contact with the patient's skin at the traditional auscultation point for the pulmonic valve. Detected signals are manipulated in the same fashion noted in the "operation" of the present invention. The signals may be viewed and analyzed by medical personnel at any number of points during this data manipulation process to allow for the implementation of a treatment regimen. Where the sound emitted by either semilunar valve is of a higher than normal frequency, this is indicative of increased blood pressure in the corresponding circuit; that is, an increased frequency emitted by the aortic semilunar valve is indicative of higher than normal systemic blood pressure, while an increased frequency being emitted by the pulmonary semilunar valve is indicative of higher than normal pulmonary blood pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

1 Figure 1 is a schematic representation of the overall architecture and user interface of the
2 present invention.

3 Figure 2a depicts an exploded, oblique view of the sensor assembly.

4 Figure 2b depicts an exploded, side view of the sensor assembly.

5 Figure 3 depicts an exploded, oblique view of an alternative embodiment of the sensor
6 assembly.

7 Figure 4 depicts a circuit diagram of the electronic module, data cable and data
8 acquisition module.

9 Figure 5 depicts a circuit diagram of greater detail, comprising the electronic module,
10 data cable and data acquisition module.

11 Figure 6 depicts a circuit diagram of still greater detail, comprising the electronic module,
12 data cable and data acquisition module.

13 Figure 7 depicts the frequency response of a tailored bandpass amplifier.

14 Figure 8 illustrates the simultaneous display of ECG and acoustic signal data.

15 Figure 9a illustrates an acoustic amplitude vs. time display mode.

16 Figure 9b illustrates a relative amplitude vs. frequency display mode.

17 Figure 9c illustrates a frequency vs. time display mode.

18 Figure 10 is a flow chart illustrating the operation of the present invention.

19 Figure 11 graphs the relationship of second heart sound frequency vs. blood pressure.
20

21 DETAILED DESCRIPTION

22
23 The present invention provides an apparatus, operation and method to passively and non-
24 invasively measure systemic and pulmonic blood pressure through detection, identification and
25 characterization of the acoustic signature associated with heart valve closure.
26

27 APPARATUS

28
29 Referring to Figure 1, the overall architecture of the present invention is described.
30 Patient physiologic signals, such as acoustic vibrations or electrical impulses, are detected by
31 sensor assembly 102. In an alternative embodiment a plurality of sensor assemblies can be used

1 to either simultaneously obtain signals from various locations of the body or to simultaneously
2 obtain signals from both the patient and the environment. Sensor assembly **102** is connected to
3 data acquisition means **103**.

4 Data acquisition means **103** comprises preamplifier **114**, audio amplifier **116**, and analog-
5 to-digital converter **118**. Preamplifier **114** electronically isolates the transducer, detects the
6 electronic signals, and sends them to audio amplifier **116** and to analog-to-digital converter **118**.
7 Audio amplifier **116** drives one or more sets of high-fidelity earphones **120**. Analog-to-digital
8 converter **118** samples the analog signal and converts it to a binary number for each time sample.
9 Data acquisition means **103** is connected to signal processing means **104**.

10 Signal processing means **104** is a general-purpose microprocessor. Signal processing
11 means **104**, also has means for video display of information, such as monitor **112**. Signal
12 processing means **104** is connected to electronic data storage means **106**, operator input means
13 **107**, hard copy reproduction means **108** and remote connection means **110**.

14 Various types of electronic data storage are known to those skilled in the art. In
15 alternative embodiments electronic data storage means **106** comprises: internal hard disk drive,
16 external hard disk drive, floppy disks, digital audio tape, magneto-optical storage or CD ROM.
17 Likewise, various types of operator input means are known to those skilled in the art. In
18 alternative embodiments operator input means **107** comprises: keyboard, mouse, voice detector
19 or other means. Hard copy reproduction means **108** provides copies of images displayed on
20 monitor **112** for purposes such as maintaining medical records, assisting consultations, and
21 assisting data processing and review. Remote connection means **110** is a modem. In alternative
22 embodiments, the system of the present invention may be directly linked to a network via a
23 network interface card or other suitable means. Thus a modem may not always be necessary.

24 In an alternative sensor assembly embodiment, sensor assembly **102** can detect both
25 physiologic and background signals. In another alternative sensor assembly embodiment, one
26 side of sensor assembly **102** comprises an audio transducer which is in contact with the skin
27 while a second audio transducer on the opposite side faces away from the patient. This second
28 transducer is designed to acquire ambient sounds in synchronism with the sounds reaching the
29 transducer in contact with the patient's skin to reject common mode signals reaching both
30 transducers. By adding the environmental signals out of phase with the signals acquired from the

1 patient, the sounds in common to both transducers are effectively canceled. In yet another
2 alternative sensor assembly embodiment the target frequency range for data acquisition is about
3 200 to 2000 Hz. In another alternative sensor assembly embodiment, the target frequency range
4 for signal acquisition is about 400 hertz.

5 In an alternative preamplifier embodiment, preamplifier **114** demonstrates low-noise data
6 acquisition and proper impedance matching.

7 In an alternative analog-to-digital converter embodiment analog-to-digital converter **118**
8 has a sample rate about 4 to 48 KHz. In yet another alternative analog-to-digital converter
9 embodiment, analog-to-digital converter **118** has a sample rate of about 44 KHz. In another
10 alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a
11 resolution of about 16 bits. In yet another alternative analog-to-digital converter embodiment,
12 analog-to-digital converter **118** has a linearity about ± 0.005 percent of full scale. In another
13 alternative analog-to-digital converter embodiment, analog-to-digital converter **118** has a sample
14 length of about one to sixty seconds. In yet another alternative analog-to-digital converter
15 embodiment, analog-to-digital converter **118** has an operator selectable sample length.

16 In an alternative earphones embodiment, earphones **120** have separate volume controls.

17 In an alternative signal processing means embodiment, signal processing means **104** is a
18 computer with a central processing unit. In another alternative signal processing means
19 embodiment, signal processing means **104** is an IBM compatible personal computer using an
20 INTEL processor (386, 486, Pentium), having a minimum of 8 MB RAM memory and a
21 minimum hard disk size of 500 MB. In yet another alternative signal processing means
22 embodiment, signal processing means **104** is a Macintosh PowerPC.

23 In an alternative monitor embodiment, monitor **112** has a minimum display size of 600 X
24 400 pixels and a minimum monitor **112** display depth of eight bits. In yet another alternative
25 monitor embodiment, monitor **112** is a high resolution EGA or VGA color display monitor.

26 In an alternative signal processing means embodiment, signal processing means **104**
27 comprises a sound card. In another alternative signal processing means embodiment, the sound
28 card comprises a "Tahiti" multiple channel computer sound card manufactured by Turtle Beach,
29 although sound cards such as the Pro Audio 1b (Media Vision) can also be used.

30 In an alternative hard copy reproduction means embodiment, hard copy reproduction

1 means **108**, is a printer. In another alternative hard copy reproduction means embodiment, hard
2 copy reproduction means **108** is a printer capable of generating a variety of different graphic
3 displays. In yet another alternative hard copy reproduction means embodiment, hard copy
4 reproduction means **108** is a laser printer.

5 In an alternative remote connection means embodiment, remote connection means **110** is
6 an internal or external, high speed modem. In another alternative remote connection means
7 embodiment, remote connection means **110** has a speed of at least 14.4 kilobytes per second.

8 Referring to Figure 2a, an oblique view of an embodiment of sensor assembly **102** is
9 shown. Figure 2b depicts a side view of an embodiment of sensor assembly **102**. Housing **302**
10 comprises a sound deadening material having sufficient mass to dampen high frequency ambient
11 disturbances and hold the sensor assembly in contact with the patient through gravity. Housing
12 **302** has housing front **304** and housing back **306**. Rim **308** is located on the periphery of housing
13 front **304**. First indentation **310** runs parallel and adjacent to the inside of rim **308**. Second
14 indentation **312** runs parallel and adjacent to the inside of first indentation **310**. Bore **312** is
15 approximately centrally located within second indentation **312** and is shaped and sized in
16 conformity to the shape and size of electronic module **314**. Electronic module **314** nests within
17 bore **312** of housing **302**. As will be further discussed, signal detection and processing circuitry
18 are incorporated within electronic module **314**.

19 Shock dampener **316** is positioned adjacent to first indentation **310**. Mounting means **318**
20 is positioned adjacent to shock dampener **316**. Transducer **320** is positioned within mounting
21 means **318**. Transducer **320** converts detected signals into electronic signals. Acoustic coupling
22 **322** is positioned adjacent to transducer **320**. Acoustic coupling **322** serves to dilinearize
23 excitation response and reduce dynamic range.

24 Once assembled, housing **302** is closed to the ambient environment with back cover **324**.
25 Sensor assembly **102** comprising all the individual sensor elements, is assembled and sealed to
26 form a single complete unit.

27 In an alternative housing embodiment, housing **302** is composed of nickel plated
28 aluminum, but can be any material having sufficient mass to dampen high frequency ambient
29 disturbances and hold the sensor in contact with the patient through gravity.

30 In an alternative sensor assembly embodiment, when electronic module **314** nests within

bore **312** of housing **302**, top **316** of electronic module **314** is flush with second indentation **312**.

In an alternative shock dampener embodiment shock dampener **316** is an "O" ring.

In an alternative mounting means embodiment, mounting means **318** is a plastic mounting ring.

In an alternative transducer embodiment, transducer **320** is a piezoelectric disk. In another alternative transducer embodiment, transducer **320** has a high impedance. In yet another alternative transducer embodiment, transducer **320** has an impedance of about 470 Kohms. In another alternative transducer embodiment, transducer **320** has high efficiency as compared with conventional electromagnet type speakers. In yet another alternative transducer embodiment, transducer **320** is ultra thin and lightweight. In another alternative transducer embodiment, transducer **320** has a frequency range of about 500 - 20,000 Hz. In yet another alternative transducer embodiment, transducer **320** has a capacitance at 120 Hz of about 60 ± 30 % nF. In another alternative transducer embodiment, transducer **320** current leakage is limited to about one micro ampere.

In an alternative acoustic coupling embodiment, acoustic coupling **322** is impedance matched, and serves to provide a low-loss acoustic transmission coupling between the skin of the patient and transducer **320**, thereby minimizing signal loss across the subject-detector interface. In another alternative acoustic coupling embodiment, acoustic coupling **322** is a parametric acoustic transducer. In yet another acoustic coupling embodiment, acoustic coupling **322** has a high conduction coefficient. In another alternative acoustic coupling embodiment, acoustic coupling **322** is made of latex foam. In yet another alternative acoustic coupling embodiment, acoustic coupling **322** is logarithmically attenuated, having low transmission at low frequencies and high transmission at high frequencies.

Referring to Figure 3 an oblique exploded view of an alternative embodiment of sensor assembly **102** is shown. Housing **402** comprises a sound deadening material having sufficient mass to dampen high frequency ambient disturbances and hold the sensor assembly in contact with the patient through gravity. Housing **402** has housing front **404** and housing back **406**. First rim **408** is located on the periphery of housing front **404**. Second rim **410** is located on the periphery of housing back **406**. First indentation **412** runs parallel and adjacent to the inside of first rim **408**. Second indentation **414** runs parallel and adjacent to the inside of first indentation

1 **412**. Third indentation **416** runs parallel and adjacent to the inside of second rim **410**. Fourth
2 indentation **418** runs parallel and adjacent to the inside of third indentation **416**. First bore **420** is
3 approximately centrally located within second indentation **414** and is shaped and sized in
4 conformity to the shape and size of first electronic module **422**. Second bore **440** is
5 approximately centrally located within fourth indentation **418** and is shaped and sized in
6 conformity to the shape and size of second electronic module **442**. First electronic module **422**
7 nests within first bore **420** of housing **402**. Second electronic module **442** nests within second
8 bore **440** of housing **402**. As will be further discussed, signal detection and processing circuitry
9 are incorporated within first and second electronic module **422**, **442**.

10 First shock dampener **424** is positioned adjacent to first indentation **412**. Second shock
11 dampener **426** is positioned adjacent to third indentation **416**. First mounting means **428** is
12 positioned adjacent to first shock dampener **424**. Second mounting means **430** is positioned
13 adjacent to second shock dampener **426**. First transducer **432** is positioned within first mounting
14 means **428**. Second transducer **434** is positioned within second mounting means **430**. First
15 transducer **432**, converts detected physiologic signals into electronic signals. Second transducer
16 **434**, converts detected environmental or background signals into electronic signals. First
17 acoustic coupling **436** is positioned adjacent to first transducer **432**. Second acoustic coupling
18 **438** is positioned adjacent to second transducer **434**. First and second acoustic coupling **436**, **438**
19 serve to dilinearize excitation response and reduce dynamic range.

20 In an alternative housing embodiment, housing **402** is composed of nickel plated
21 aluminum.

22 In an alternative shock dampener embodiment, first and second shock dampener **424**, **426**
23 is an "O" ring.

24 In an alternative mounting means embodiment, first and second mounting means **428**,
25 **430** is a plastic mounting ring.

26 In an alternative transducer embodiment, first and second transducer **432**, **434** is a
27 piezoelectric disk. In another alternative transducer embodiment, first and second transducer
28 **432**, **434** has a high impedance. In yet another alternative transducer embodiment, first and
29 second transducer **432**, **434** has an impedance of about 470 Kohms. In another alternative
30 transducer embodiment, first and second transducer **434**, **434** has high efficiency as compared

1 with conventional electromagnet type speakers. In yet another alternative transducer
2 embodiment, first and second transducer **432**, **434** is ultra thin and lightweight. In another
3 alternative transducer embodiment, first and second transducer **432**, **434** has a frequency range
4 of about 5 - 2,000 Hz. In yet another alternative transducer embodiment, first and second
5 transducer **432**, **434** has a capacitance at 120 Hz of about 60 ± 30 % nF. In another alternative
6 transducer embodiment, first and second transducer **432**, **434** current leakage is limited to about
7 one micro ampere.

8 In an alternative acoustic coupling embodiment, first and second acoustic coupling **436**,
9 **438**, is impedance matched, and serves to provide a low-loss acoustic transmission coupling
10 between the skin of the patient and first transducer **432**, thereby minimizing signal loss across the
11 subject-detector interface. In another alternative acoustic coupling embodiment, first and second
12 acoustic coupling **436**, **438** is a parametric acoustic transconductor. In yet another acoustic
13 coupling embodiment, first and second acoustic coupling **436**, **438** has a high conduction
14 coefficient. In another alternative acoustic coupling embodiment, first and second acoustic
15 coupling **436**, **438** is made of latex foam. In yet another alternative acoustic coupling
16 embodiment, acoustic coupling **322** is logarithmically attenuated, having low transmission at low
17 frequencies and high transmission at high frequencies.

18 Referring to Figure 4, electronic module **314**, transducer **320**, data cable **502**, and data
19 acquisition module **504** of the present invention are shown in schematic form. In combination,
20 first resistor **506**, semiconductor device **508**, second resistor **510**, and first capacitor **512**
21 comprise electronic module **314**. Electronic module **314** performs functions such as signal
22 amplification, and filtering. Transducer **320** is connected in parallel with first resistor **506**,
23 second resistor **510**, first capacitor **512**, and semiconductor **508**. Semiconductor **508** serves to
24 modulate current. First capacitor **512** provides gain and source decoupling for semiconductor
25 **508**.

26 In an alternative first resistor embodiment, first resistor **506** provides a matching load to
27 transducer **320**. In another alternative first resistor embodiment first resistor **506** has a resistance
28 of 470 Kohms.

29 In an alternative second resistor embodiment, second resistor **510** is about 10 Kohms.

30 In an alternative semiconductor embodiment, semiconductor **508** is field effect transistor.

1 In another alternative semiconductor embodiment, semiconductor **508** is a field effect transistor
2 with an N-type base.

3 In an alternative first capacitor embodiment, first capacitor **512** is 60 microfarads and is
4 connected to ground.

5 Figure 5 depicts a circuit diagram of the electronic module, data cable and data
6 acquisition module in greater detail. The circuit comprises electronic module **314**, transducer
7 **320**, data cable **502**, and data acquisition module **504**. Data cable **502** couples electronic module
8 **314** to data acquisition module **504**. Data acquisition module **504** comprises an amplifier. As
9 depicted in Fig. 5, highpass filter **606** is followed by lowpass filter **608** having a DC injection
10 point. The amount of DC injection is made variable by value selection of variable resistor **610**.
11 In an alternative value selection embodiment, value selection is determined by the practitioner.
12 In yet another alternative value selection embodiment, value selection is determined
13 automatically by the signal processing means in conformity with predetermined parameters.

14 In an alternative data cable embodiment, data cable **502** is twisted pair **602**, wherein two
15 insulated wires are twisted forming a flexible line without the use of spacers. In another
16 alternative data cable embodiment, data cable **502** is shielded pair **604**, wherein two parallel
17 conductors are separated from each other and surrounded by a solid dielectric. In this alternative
18 embodiment, the conductors are contained within a copper-braid tubing that acts as a shield. The
19 assembly is covered with a rubber or flexible composition coating to protect the line against
20 moisture and friction. There are two advantages of this alternative embodiment: (1) the
21 capacitance between each conductor and ground is uniform along the entire length of the line;
22 and (2) the wires are shielded against pickup of stray electric fields. In yet another alternative
23 embodiment shielded pair **604** data cable **502** is connected to sensor housing **610** and to ground
24 as a means for reducing electrical noise and increasing patient safety.

25 In an alternative data acquisition module embodiment, data acquisition module **504** has a
26 low frequency response from about 10 Hz to a crossover point at 100 Hz, rising to a level 20 dB
27 higher from about 600 Hz to 2 KHZ, then declining steadily beyond that point. In another
28 alternative data acquisition module embodiment, data acquisition module **504** comprises a
29 voltage gain, variable from zero to fifty, allowing recovery of low-level sounds from 600 to about
30 2000 Hz while preserving the ability to measure low-frequency signals having a relatively high

1 amplitude, without amplifier saturation.

2 In an alternative highpass filter embodiment, highpass filter **606** has a gain of about 7,
3 and lowpass filter **608** drives an output amplifier with a gain of about 7. In another alternative
4 highpass filter embodiment the overall voltage gain available with the gain potentiometer at
5 maximum will be about 50. An advantage of this alternative embodiment is the ability to reject a
6 narrow range of frequencies in a notch caused by the phase delay in the components of highpass
7 filter **606**. In an alternative highpass filter embodiment this notch is set at 100 Hz. In another
8 alternative highpass filter embodiment this notch is set at about 50 - 60 Hz, thereby providing a
9 measure of hum rejection

10 Figure 6 depicts a circuit diagram of the electronic module, data cable and data
11 acquisition module in greater detail. The circuit comprises electronic module **314**, transducer
12 **320**, data cable **502**, and data acquisition module **504**. Three stage resistor/capacitor network **702**
13 gives a total of about 180 degrees of phase shift at a design frequency of about 100 Hz that is
14 related to the combined resistor/capacitor time constants of the network. Field effect transistor
15 **508** input is AC-coupled to the four-pole lowpass filter **608** formed by a single 747-type
16 operational amplifier pair.

17 Figure 7 depicts an idealized shape of an amplifier having low-frequency response from
18 first point **802** to crossover point **804** and having higher frequency response of predetermined
19 level **806**, from second point **808** to third point **810**. In an alternative embodiment, first point
20 **802** is about 10 Hz, crossover point **804** is about 100 Hz, predetermined level **806** is about 20 dB,
21 second point **808** is about 600 Hz and third point **810** is about 2 KHz. In yet another alternative
22 embodiment, crossover point **804** is about 60 Hz.

23 Figure 8 further depicts the response of the tailored bandpass amplifier, plotting
24 amplitude **902** vs. frequency **904** of basic heart sounds **906** and sounds of interest **908**. In
25 alternative embodiments, the response of sounds of interest **908** may be set at varying levels **910**.

26 Figure 9 depicts the simultaneous display of electrocardiogram and sonospectrography
27 data. In the simultaneous display mode, the present invention provides for plotting
28 electrocardiogram data and sonospectrography data as a function of intensity **1002** and time
29 **1004**, with digital markers **1006** to allow the visual correlation of points of signal activity that
30 may be common to both signals. As an example, the electrocardiogram pulse at **1008** can be

1 visually correlated with a select part of the acoustic signal **1010** and differentially measured to
2 within 23 millionths of a second. This allows an operator who may be less familiar with acoustic
3 signatures to correlate the electrocardiogram signal, which may be well understood, with the
4 acoustic signal.

5 Referring to Figures 10a, 10b, and 10c, the display methodology of the present invention
6 is shown. The present invention provides a means to simultaneously display the signal of interest
7 in a variety of different forms. In Figure 10a, the signal of interest of the present invention is
8 presented as a simple time series, with acoustic amplitude **1102** on the vertical scale and time
9 **1104** on the horizontal scale. In Figure 10b, the signal of interest of the present invention is
10 presented as a time and frequency display, with relative amplitude **1106** of each slice of the
11 frequency spectrum on the vertical scale and frequency spectrum **1108** on the horizontal display.
12 In Figure 10c, the signal of interest of the present invention is presented with frequency **1110** on
13 the vertical axis, time **1112** on the horizontal axis, and relative amplitude plotted in different
14 color hues (not shown) and/or grey scale intensity.

15 Having thus described the basic concept of the apparatus of the invention, it will be
16 readily apparent to those skilled in the art that the foregoing detailed disclosure is intended to be
17 presented by way of example only, and is not limiting. Various alterations, improvements and
18 modifications will occur and are intended to those skilled in the art, but are not expressly stated
19 herein. For example, while cardiovascular monitoring is a key aspect of the invention, the
20 techniques described herein are equally applicable to the monitoring of other body organs and
21 regions of the body of both humans and animals and thus may also find utility in the veterinary
22 sciences. These modifications, alterations and improvements are intended to be suggested
23 hereby, and are within the spirit and scope of the invention.

24 OPERATION

25
26
27 Figure 11 depicts the operation of the apparatus of the present invention with associated
28 hardware and software. At step **1202**, start-up procedures are performed such as initialization,
29 calibration, sensor selection, patient parameter input, and buffer clearing, among others. Upon
30 completion of these start-up procedures steps **1204** and **1206** are initiated. At step **1204**, sensor
31 **102** provides patient physiologic signals for signal processing. In an alternative embodiment,

1 sensor **102** can include electrocardiogram sensors and acoustic sensors. At step **1206** acoustic
2 sensors are used to detect background or ambient noise.

3 Next, at step **1208**, the detected signals are passed to individual data acquisition modules
4 which contain means for signal filtering, impedance matching, amplification, and buffering.
5 These functions are performed by the components of the circuitry illustrated in Figs. 4-6.

6 At step **1210**, the signals from the ambient noise acoustic sensor acquired in step **1206**,
7 are processed and subtracted from the signals from the desired sensor of step **1204** in a noise
8 cancellation process to reduce the effect of ambient noise from the patient's environment.

9 At step **1212**, the signal undergoes additional signal conditioning and processing. The
10 purpose of this conditioning step is to convert the analog signal to digital, provide adjustable
11 decimation with a sampling rate suitable to avoid biasing, provide adjustable smoothing,
12 averaging and peak holding. In an alternative embodiment the signal conditioning and
13 processing of step **1212** is performed by a sound card which typically has the following
14 capabilities: (1) a sample rate selectable from about 4 K to 44 K; (2) a sample size of about 16
15 bits; (3) capable of analog to digital conversion; (4) capable of digital to analog conversion; and
16 (5) possesses IBM computer bus compatibility such as ISA, EISA, PCI, etc. In yet another
17 alternative embodiment the sound card used comprises a "Tahiti" multiple channel Sound Card
18 manufactured by Turtle Beach. Step **1230** allows for the intermediate output and display of the
19 desired signal following the signal conditioning and processing of step **1212**. The display is
20 accomplished by selection of a desired display mode and subsequent display on the monitor **112**.
21 The output of step **1212** is of a time series and is suitable for display selection as in Figure 10a.

22 At step **1214**, the digitized and conditioned data is subjected to a sliding fast Fourier
23 transformation. The output of step **1214** is of time and frequency and is suitable for display
24 selection according to Figures 10b or 10c.

25 At step **1216**, time domain components of the data passes through a time domain
26 correlator and feature extraction process. In a similar fashion, in step **1218**, the frequency
27 domain components of the data passes through a frequency domain correlator and feature
28 extractor. In step **1220**, the outputs from the time domain correlator and feature extraction
29 process of step **1216** and the frequency domain correlator and feature extractor of step **1218** are
30 compared to a reference pattern and feature library, to determine whether the features contained

1 within the signal of interest match known disease modalities as recorded and maintained within
2 the reference pattern and feature library.

3 At step 1222, the outputs from the time domain correlator and feature extraction process
4 of step 1216, the frequency domain correlator and feature extractor process of step 1218 and the
5 results from the reference pattern and feature library comparison of step 1220 are subjected to a
6 recognition logic decision, where a determination is made as to whether a disease or adverse
7 condition is indicated. At step 1224, the new disease modality indicated in the recognition logic
8 decision of step 1222 is then used to update the reference pattern and feature library of step 1220.
9 In step 1226 a desired display mode such as depicted in Figures 10a, 10b and 10c is chosen for
10 subsequent display on the monitor 112. At step 1228 the process is either terminated at step
11 1240 or begun anew at step 1202.

12 The preceding descriptions of the operation of the present invention are merely
13 illustrative. In various embodiments of the disclosed invention operational steps may be added,
14 eliminated, performed in parallel or performed in a differing order.

16 METHOD

17
18 Sonospectrography can be used as a primary source of auscultatory information in a
19 routine physical examination or in population screening. Sonospectrography can be used in
20 cardiology and general medicine for the detection of functional and organic disorders of the heart
21 such as congenital defects, valve function, diseases of the pericardium and myocardium and
22 systemic and pulmonary hypertension. Sonospectrography can also be used as a traditional
23 stethoscope to capture sounds generated by other organs, such as the lungs, trachea, larynx, liver
24 and carotid arteries.

25 Elevated blood pressure has a number of causes. Regardless of the cause, however,
26 recent testing at the Uniformed Services University of Health Sciences shows that there is a
27 change in the frequency spectrum of both the aortic and pulmonary semilunar valve sounds that
28 is directly correlated to change in blood pressure of the associated systemic or pulmonary
29 circulatory system. This correlation was shown to be both measurable and repeatable in testing
30 on animals having systemic and pulmonary circulatory systems comparable to the human system.

31 Elevated blood pressure increases back pressure at associated heart valves. This

Bpspec-PCT.WPD: December 3, 1997

1 increased back pressure results in more rapid closure of the heart valves and a resultant audible
2 "snap" of the valve leaflets. The acoustic signature that is associated with those heart valve
3 sounds has elevated frequency components as compared to the signature associated with heart
4 valves operating under normal blood pressures. As the blood pressure increases, this frequency
5 component also increases. It has been determined that this change in the frequency component
6 is transitory and returns to normal when the blood pressure returns to normal.

7 Thus, where the sound emitted by the aortic semilunar valve is of an increased frequency,
8 this is indicative of higher systemic blood pressure. Similarly, where the sound emitted by the
9 pulmonary semilunar valve is of an increased frequency, this is indicative of higher pulmonic
10 blood pressure. Through the use of the apparatus of the present invention, it is possible to detect
11 and record sounds originating from the aortic and pulmonary semilunar valves.

12 In practice, a sensor assembly is placed in contact with the patient. One side of the sensor
13 assembly contains an acoustic coupler that is placed in contact with the patient's skin at the
14 traditional auscultation point for the valve of interest, while a second acoustic coupler on the
15 opposite side faces away from the patient. This second acoustic coupler is designed to acquire
16 background sounds in synchronism with the acoustic coupler in contact with the patient's skin to
17 reject common mode signals reaching both couplers. While breathing normally the sounds of the
18 aortic and/or pulmonary semilunar valves are acquired, preamplified and sent to a plurality of
19 locations.

20 One analog signal is sent directly to an audio amplifier and high fidelity earphones. A
21 second analog signal is sent through a gain control potentiometer to an analog to digital
22 converter. The data is digitized and displayed in real time on a monitor. Visual feedback from
23 the monitor allows a precise setting of the gain control by the physician for the optimum
24 acquisition of data. In an alternative embodiment, an electronic strip chart is used in the precise
25 setting of the gain control. The physician adjusts gain control to maximize the dynamic range of
26 the captured signal.

27 In one embodiment, sounds are filtered normally. In an alternative embodiment, sounds
28 are filtered to de-emphasize interfering responses prior to being sent to the earphones or the
29 analog to digital converter. Data can be stored digitally, recalled for future analysis or
30 transmitted to another location.

31 Referring to Figure 12, data from recent in-vivo testing on animal subjects at the

1 Uniformed Services University of Health Sciences is shown. The subject had a pressure catheter
2 emplaced to provide actual pressure readings, and the present invention detected, and processed
3 the acoustic signature data from the second heart sounds. Figure 12 plots the relationship
4 between second heart sound A2 **1302**, and blood pressure **1304**. As shown, where there is a rise
5 in the frequency of second heart sound **1302**, there is a corresponding rise in systolic pressure
6 **1306**, mean pressure **1308** and diastolic pressure **1310**.

7 The subject whose pressure/frequency relationship is depicted in Figure 12, had a resting
8 systolic pressure of about 120 mm Hg, a resting diastolic pressure of about 77 mm Hg, and a
9 predominant second heart sound frequency of 28.5 Hz. The mean blood pressure was thus about
10 90 mm Hg at 28.5 Hz. As the subject's blood pressure was artificially increased, the associated
11 frequency components of the second heart sound correspondingly increased. Systolic pressure
12 **1306** of the subject reached about 165 mm Hg, diastolic pressure **1310** reached about 85 mm Hg,
13 and frequency of second heart sound **1302** reached 36. Mean pressure **1308** reached about 115
14 mm Hg. The slope of this mean pressure/frequency curve is approximately 2 mm Hg per Hz.
15 This pressure/frequency correlation was demonstrated in each animal subject tested.

16 Across a population, measurement of the sound frequency associated with the closure of
17 the aortic and pulmonary semilunar valves will allow an estimate of the mean systemic and
18 pulmonary blood pressure. Specifically, using a range of pressure/frequency curves collected
19 from population samples, the present invention will allow an estimate of the mean systemic and
20 pulmonary pressure with a passive and non-invasive acoustic measurement of the acoustic
21 signature of the semilunar valve closure. As an example, if the mean pressure data curve **1307** in
22 Figure 12 presented an accumulated average from the population, then measurement of a
23 pulmonary semilunar valve closure sound frequency of 36 Hz **1309** would provide an estimate
24 that the mean pulmonic pressure was 115 mm Hg **1311**. In an otherwise asymptomatic patient,
25 this might provide sufficient clinical justification for use of an invasive blood pressure catheter,
26 with the attendant risk and cost, to confirm the pulmonic pressure.

27 Although the method of the present invention has been described in detail for purpose of
28 illustration, it is understood that such detail is solely for that purpose, and variations can be made
29 therein by those skilled in the art without departing from the spirit and scope of the invention.
30 The apparatus, operation and method of the present invention is defined by the following claims.

1 **WHAT IS CLAIMED IS:**

- 2
- 3 1. An apparatus for monitoring blood pressure comprising:
- 4 a means for detecting audio signals;
- 5 a means for signal processing connected to the signal detecting means;
- 6 a means for signal storage connected to the signal processing means; and
- 7 a means for monitoring, connected to the signal processing means.
- 8 2. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
- 9 audio signal detecting means is a sensor assembly.
- 10 3. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
- 11 audio signal detecting means is a plurality of sensor assemblies.
- 12 4. An apparatus for monitoring blood pressure as claimed in claim 2, wherein the
- 13 sensor assembly comprises:
- 14 a housing having a front and a back;
- 15 an electronic module connected to the housing;
- 16 a shock dampener connected to the front of the housing;
- 17 a means for mounting connected to the housing;
- 18 a transducer connected to the mounting means;
- 19 an acoustic coupling connected to the transducer; and
- 20 a cover connected to the back of the housing.
- 21 5. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
- 22 housing further comprises a sound deadening material.
- 23 6. An apparatus for monitoring blood pressure as claimed in claim 5, wherein the
- 24 housing further comprises nickel plated aluminum.
- 25 7. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
- 26 housing further comprises:
- 27 a rim having an inside and an outside, located on the periphery of the front of the
- 28 housing;
- 29 a first indentation having an inside and an outside, that runs parallel and adjacent to the
- 30 inside of the rim;
- 31 a second indentation that runs parallel and adjacent to the inside of the first indentation;

1 and

2 a bore that is approximately centrally located within the second indentation.

3 8. An apparatus for monitoring blood pressure as claimed in claim 7, wherein the
4 electronic module nests within the bore.

5 9. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
6 shock dampener is an "O" ring.

7 10. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
8 mounting means is a plastic mounting ring.

9 11. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
10 transducer is a piezoelement.

11 12. An apparatus for monitoring blood pressure as claimed in claim 4, wherein the
12 acoustic coupling is a parametric acoustic transconductor.

13 13. An apparatus for monitoring blood pressure as claimed in claim 12, wherein the
14 parametric acoustic transconductor comprises latex foam.

15 14. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
16 signal processing means is a computer with a central processing unit.

17 15. An apparatus for monitoring blood pressure as claimed in claim 14, wherein the
18 computer with a central processing unit is an IBM compatible personal computer.

19 16. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
20 means for signal storage further comprises an array of disks.

21 17. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
22 means for signal storage further comprises an internal hard disk drive.

23 18. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
24 means for signal storage further comprises an internal hard disk drive.

25 19. An apparatus for monitoring blood pressure as claimed in claim 1, further
26 comprising:

27 a means for hard copy reproduction connected to the signal processing means.

28 20. An apparatus for monitoring blood pressure as claimed in claim 19, wherein the
29 means for hard copy reproduction further comprises a printer.

30 21. An apparatus for monitoring blood pressure as claimed in claim 1, further
31 comprising:

1 a means for remote connection connected to the signal processing means.

2 22. An apparatus for monitoring blood pressure as claimed in claim 21, wherein the
3 means for remote connection further comprises a modem.

4 23. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
5 means for monitoring further comprises a high resolution EGA color display monitor.

6 24. An apparatus for monitoring blood pressure as claimed in claim 1, wherein the
7 means for monitoring further comprises a high resolution VGA color display monitor.

8 25. An apparatus for monitoring blood pressure as claimed in claim 1, further
9 comprising:

10 a means for data acquisition connected to the signal detection means and the signal
11 processing means.

12 26. An apparatus for monitoring blood pressure as claimed in claim 25, wherein the
13 means for data acquisition comprises an amplifier.

14 27. An apparatus for monitoring blood pressure as claimed in claim 26, wherein the
15 amplifier comprises a tailored bandpass amplifier.

16 28. An apparatus for monitoring blood pressure as claimed in claim 27, wherein the
17 tailored bandpass amplifier comprises a low frequency response from a predetermined first point
18 to a predetermined second point, and a higher frequency response of a predetermined level, from
19 the predetermined second point to a predetermined third point.

20 29. An apparatus for monitoring blood pressure as claimed in claim 28, wherein the
21 predetermined level is about 20 dB.

22 30. An apparatus for monitoring blood pressure as claimed in claim 28, wherein the
23 predetermined first point is about 100 Hz, the predetermined second point is about 100 Hz and
24 the predetermined third point is about 600 Hz.

25 31. An apparatus for monitoring blood pressure as claimed in claim 28, where in the
26 predetermined second point is about 60 Hz.

27 32. A method of determining blood pressure comprising:

28 performing initialization procedures;

29 acquiring physiologic signals;

30 acquiring background signals;

31 subtracting background signals from physiologic signals creating physiologic data;

1 processing physiologic data forming a time domain output and a frequency domain data
2 output;

3 comparing the time domain output and the frequency domain output with a reference
4 pattern and feature library; and

5 determining if a disease modality is indicated.

6 33. A method of determining blood pressure as claimed in claim 32, wherein
7 performing initialization further comprises:

8 initializing system;

9 calibrating system;

10 selecting sensors;

11 inputting patient parameters; and

12 clearing buffers.

13 34. A method of determining blood pressure as claimed in claim 32, wherein
14 acquiring physiologic signals comprises acquiring acoustic signals.

15 35. A method of determining blood pressure as claimed in claim 32, wherein
16 acquiring physiologic signals comprises acquiring electric signals.

17 36. A method of determining blood pressure as claimed in claim 32, wherein the
18 physiologic signals are in an analog form, further comprising:

19 converting, the physiologic signals from the analog form to a digital form.

20 37. A method of determining blood pressure as claimed in claim 32, wherein the
21 background signals are in an analog form, further comprising the step:

22 converting the background signals from the analog form to a digital form.

23 38. A method of determining blood pressure as claimed in claim 32, wherein
24 processing further comprises:

25 applying signal conditioning and time domain averaging to the physiologic data forming
26 conditioned and averaged data;

27 formatting the conditioned and averaged data in an array creating formatted data;

28 aligning and normalizing formatted data, creating aligned and formalized data;

29 normalizing and integrating the aligned and formalized data, creating normalized and
30 integrated data, wherein said normalized and integrated data has time domain components and
31 frequency domain components;

1 passing the time domain components of the normalized and integrated data through a
2 time domain correlator and feature extraction process; and

3 passing the frequency domain components of the normalized and integrated data through
4 a frequency domain correlator and feature extractor, creating the time domain output and the
5 frequency domain output.

6 39. A method of determining blood pressure as claimed in claim 38, further
7 comprising:

8 displaying the formatted data on a monitor.

9 40. A method of determining blood pressure as claimed in claim 38, further
10 comprising:

11 displaying the aligned and normalized data on a monitor.

12 41. A method of determining blood pressure as claimed in claim 38, further
13 comprising:

14 displaying the normalized and integrated data on a monitor.

15 42. A method of determining blood pressure as claimed in claim 32, further
16 comprising:

17 updating the reference pattern and feature library.

18 43. A method of determining systemic blood pressure using sonospectrography
19 analysis comprising:

20 monitoring the frequency of a sound emitted by the aortic semilunar valve, wherein the
21 sound is detected using a sensor assembly, to monitor physiologic signals, the sensor assembly
22 comprising:

23 a housing having a front and a back;

24 an electronic module connected to the housing;

25 a shock dampener connected to the front of the housing;

26 a means for mounting connected to the housing;

27 an acoustic coupler connected to the mounting means;

28 a transducer connected to the acoustic coupler; and

29 a cover connected to the back of the housing;

30 processing the physiologic signals, the processing comprising:

31 applying signal conditioning and time domain averaging to the physiologic signals

1 to form conditioned and averaged data;
2 formatting the conditioned and averaged data in an array to create formatted data;
3 aligning and normalizing formatted data, to create aligned and formalized data;
4 normalizing and integrating the aligned and formalized data, to create normalized
5 and integrated data that has time domain components and frequency domain
6 components;
7 passing the time domain components of the normalized and integrated data
8 through a time domain correlator and feature extraction process;
9 passing the frequency domain components of the normalized and integrated data
10 through a frequency domain correlator and feature extractor, to create a time
11 domain output and a frequency domain output;
12 comparing time domain output and the frequency domain output with a reference pattern
13 and feature library; and
14 determining if a disease modality is indicated.

15 44. A method of determining systemic blood pressure using sonospectrography
16 analysis as claimed in claim 43, further comprising:

17 acquiring background signals; and
18 subtracting background signals from physiologic signals.

19 45. A sensor assembly for detecting physiological sounds comprising:

20 a housing having a front and a back;
21 an electronic module connected to the housing;
22 a shock dampener connected to the front of the housing;
23 a means for mounting connected to the shock dampener;
24 an acoustic coupler connected to the mounting means;
25 a transducer connected to the acoustic coupler; and
26 a cover connected to the back of the housing.

27 46. A sensor assembly as claimed in claim 45, wherein the housing further comprises
28 a sound deadening material.

29 47. A sensor assembly as claimed in claim 46, wherein the housing further comprises
30 nickel plated aluminum.

31 48. A sensor assembly as claimed in claim 45, wherein the housing further comprises:

1 a rim having an inside and an outside, that is located on the periphery of the front of the
2 housing;

3 a first indentation having an inside and an outside, that runs parallel and adjacent to the
4 inside of the rim;

5 a second indentation that runs parallel and adjacent to the inside of the first indentation;
6 and

7 a bore, that is approximately centrally located within the second indentation.

8 49. A sensor assembly as claimed in claim 48, wherein the electronic module nests
9 within the bore.

10 50. A sensor assembly as claimed in claim 45, wherein the shock dampener is an "O"
11 ring.

12 51. A sensor assembly as claimed in claim 45, wherein the mounting means is a
13 plastic mounting ring.

14 52. A sensor assembly as claimed in claim 45, wherein the transducer is a
15 piezoelement.

16 53. A sensor assembly as claimed in claim 52, wherein the acoustic coupling is a
17 parametric acoustic transconductor.

18 54. A sensor assembly as claimed in claim 53, wherein the parametric acoustic
19 transconductor comprises latex foam.

20 55. A sensor assembly for detecting physiological sounds comprising:

21 a housing, having a front, a back, and an interior;

22 an electronic module that nests in the interior of the housing;

23 a first shock dampener connected to the front of the housing;

24 a first mounting means connected to the first shock dampener;

25 a transducer connected to the first mounting means;

26 a first acoustic coupling connected to the transducer;

27 a second shock dampener connected to the back of the housing;

28 a second mounting means connected to the second shock dampener;

29 a second transducer connected to the second mounting means; and

30 a second acoustic coupling connected to the second transducer.

31 56. A sensor assembly as claimed in claim 55, wherein the housing further comprises

1 a sound deadening material.

2 57. A sensor assembly as claimed in claim 56, wherein the housing further comprises
3 nickel plated aluminum.

4 58. A sensor assembly as claimed in claim 55, wherein the housing further comprises:
5 a first rim having an inside and an outside, that is located on the periphery of the front of
6 the housing;

7 a first indentation having an inside and an outside, that runs parallel and adjacent to the
8 inside of the first rim;

9 a second indentation that runs parallel and adjacent to the inside of the first indentation;

10 a bore, that is approximately centrally located within the second indentation;

11 a second rim having an inside and an outside, that is located on the periphery of the back
12 of the housing;

13 a third indentation having an inside and an outside, that runs parallel and adjacent to the
14 inside of the second rim; and

15 a fourth indentation, that runs parallel and adjacent to the inside of the third indentation.

16 59. A sensor assembly as claimed in claim 58, wherein the electronic module nests
17 within the bore.

18 60. A sensor assembly as claimed in claim 58, wherein the first shock dampener is an
19 "O" ring and the second shock dampener is an "O" ring.

20 61. A sensor assembly as claimed in claim 58, wherein the first mounting means is a
21 plastic mounting ring and the second mounting means is a plastic mounting ring.

22 62. A sensor assembly as claimed in claim 58, wherein the first transducer is a
23 piezoelement and the second transducer is a piezoelement.

24 63. A sensor assembly as claimed in claim 58, wherein the first acoustic coupling is a
25 parametric acoustic transconductor and the second acoustic coupling is a parametric acoustic
26 transconductor.

27 64. A sensor assembly as claimed in claim 58, wherein the parametric acoustic
28 transconductor comprises latex foam.

29 65. An apparatus for determining blood pressure comprising:
30 an acoustic coupling, wherein the acoustic coupling provides a low-loss acoustic
31 transmission coupling between skin and a piezoelectric transducer.

1 66. An apparatus for determining blood pressure as claimed in claim 65, wherein the
2 acoustic coupling is a parametric acoustic transducer.

3 67. An apparatus for determining blood pressure as claimed in claim 65, wherein the
4 acoustic coupling has a high conduction coefficient.

5 68. An apparatus for determining blood pressure as claimed in claim 65 wherein the
6 acoustic coupling comprises latex foam.

7 69. An apparatus for monitoring blood pressure comprising:

8 an acoustic coupling;

9 a transducer connected to the acoustic coupling;

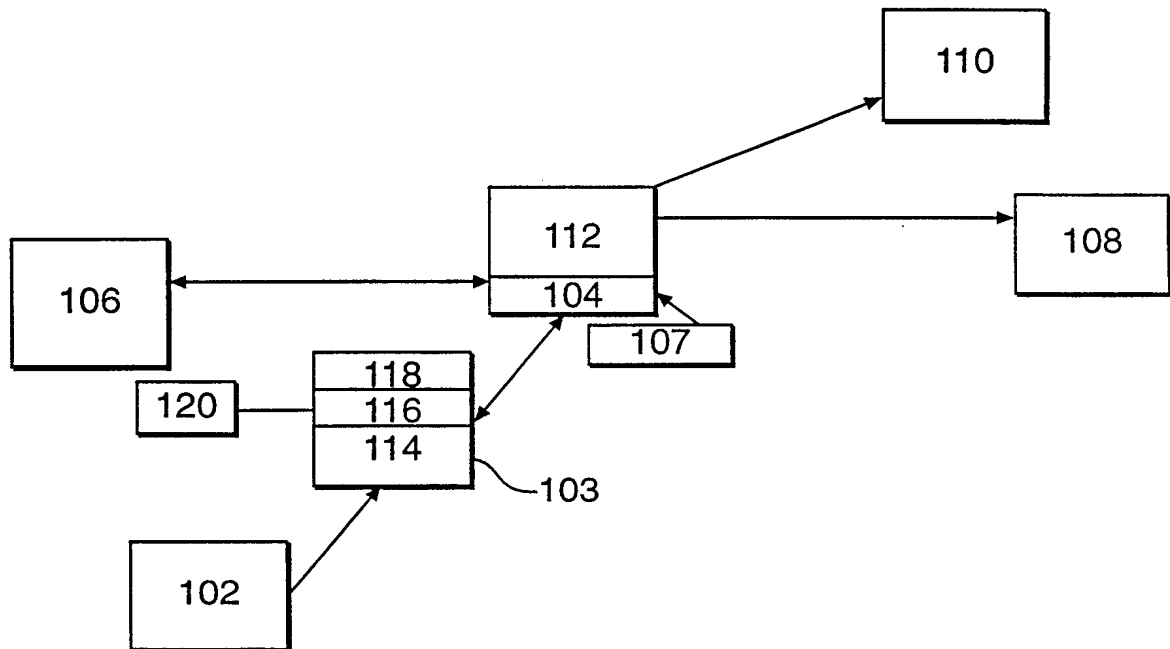
10 an electronic module connected to the transducer;

11 a data acquisition module connected to the electronic module; and

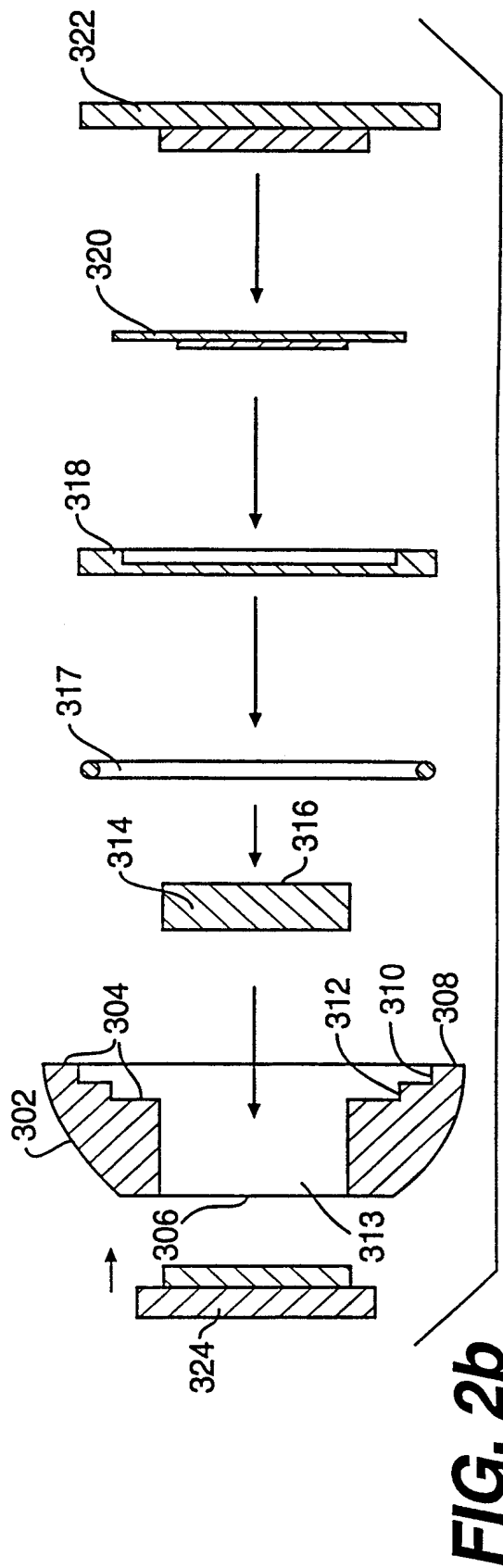
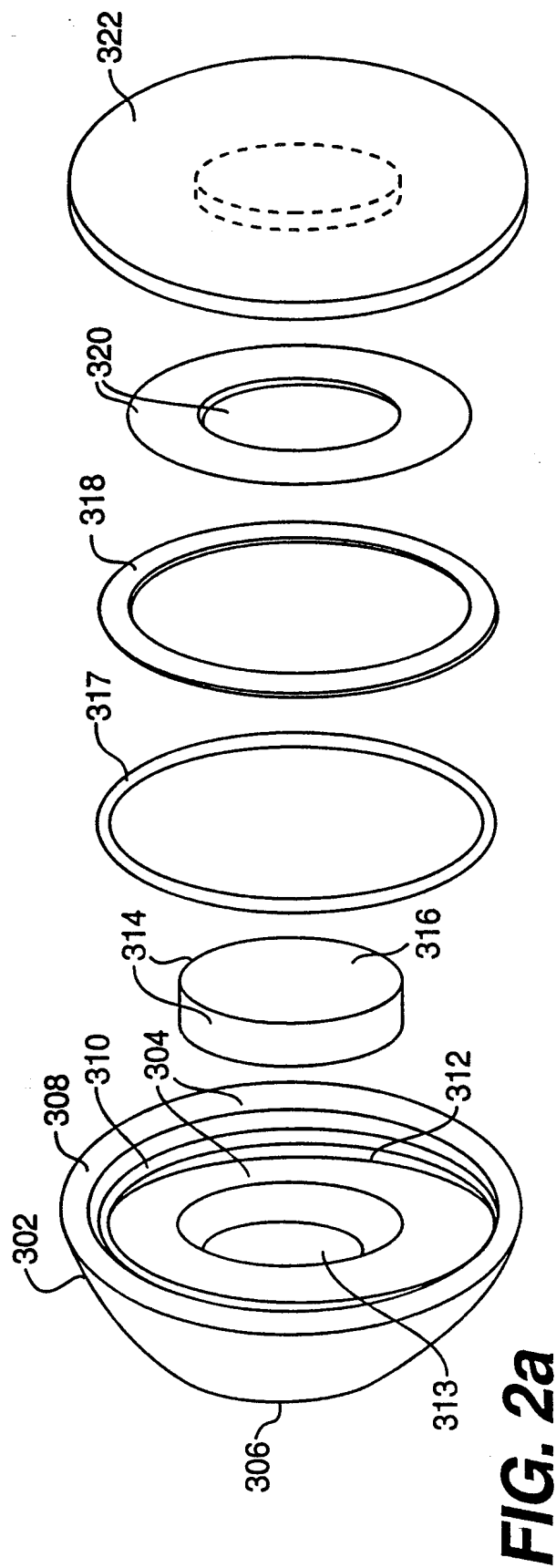
12 a data cable connected to the electronic module and the data acquisition module.

13 70. An apparatus for monitoring blood pressure as claimed in claim 69, wherein the
14 data cable is a twisted shielded pair.

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**FIG. 1**

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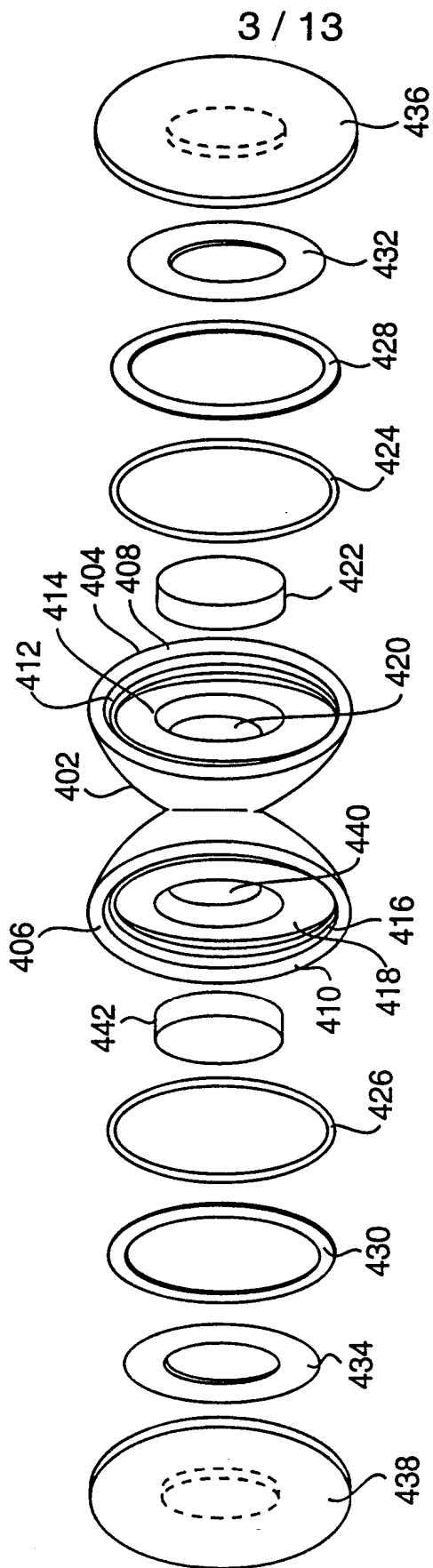


FIG. 3

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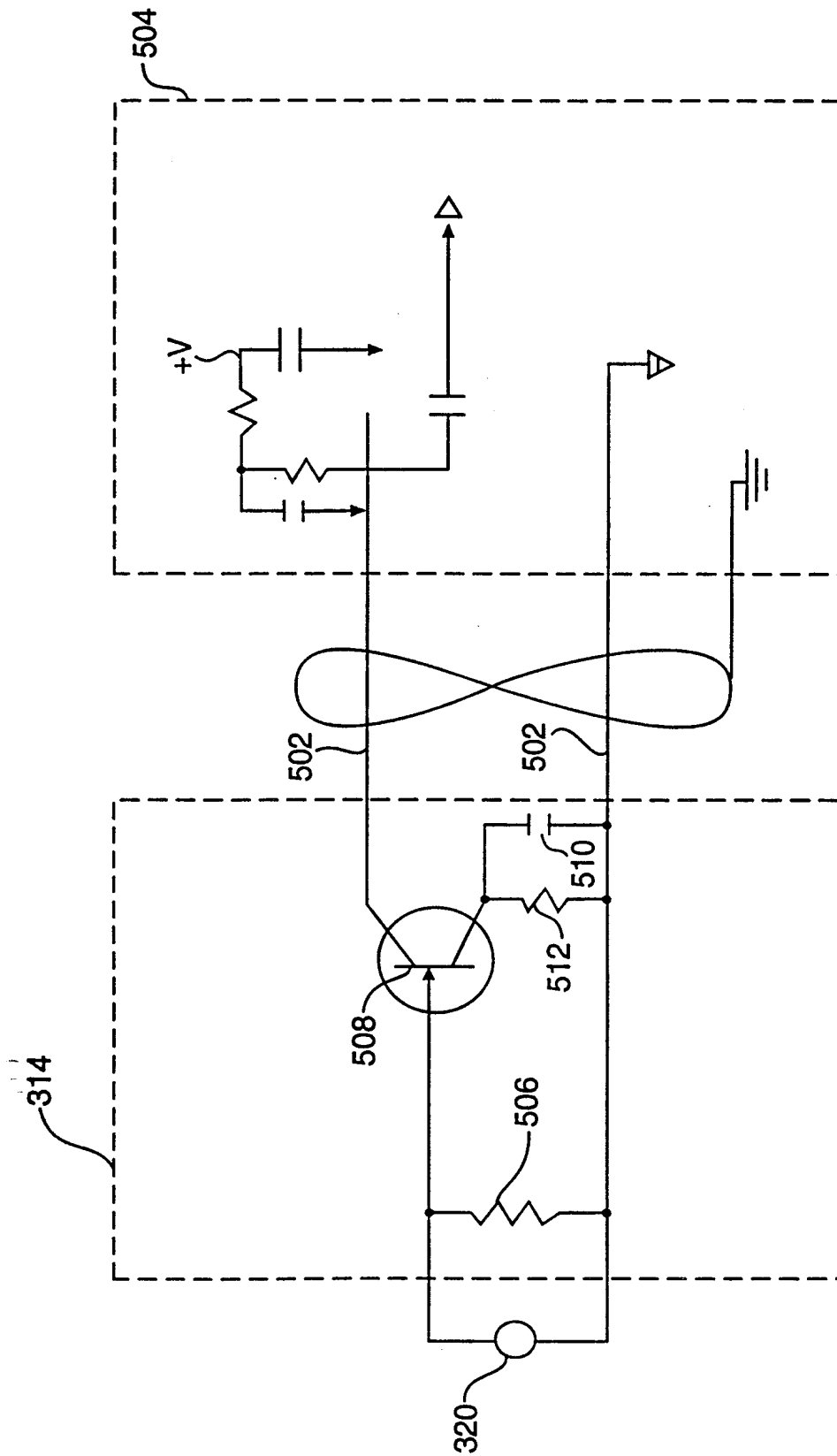


FIG. 4

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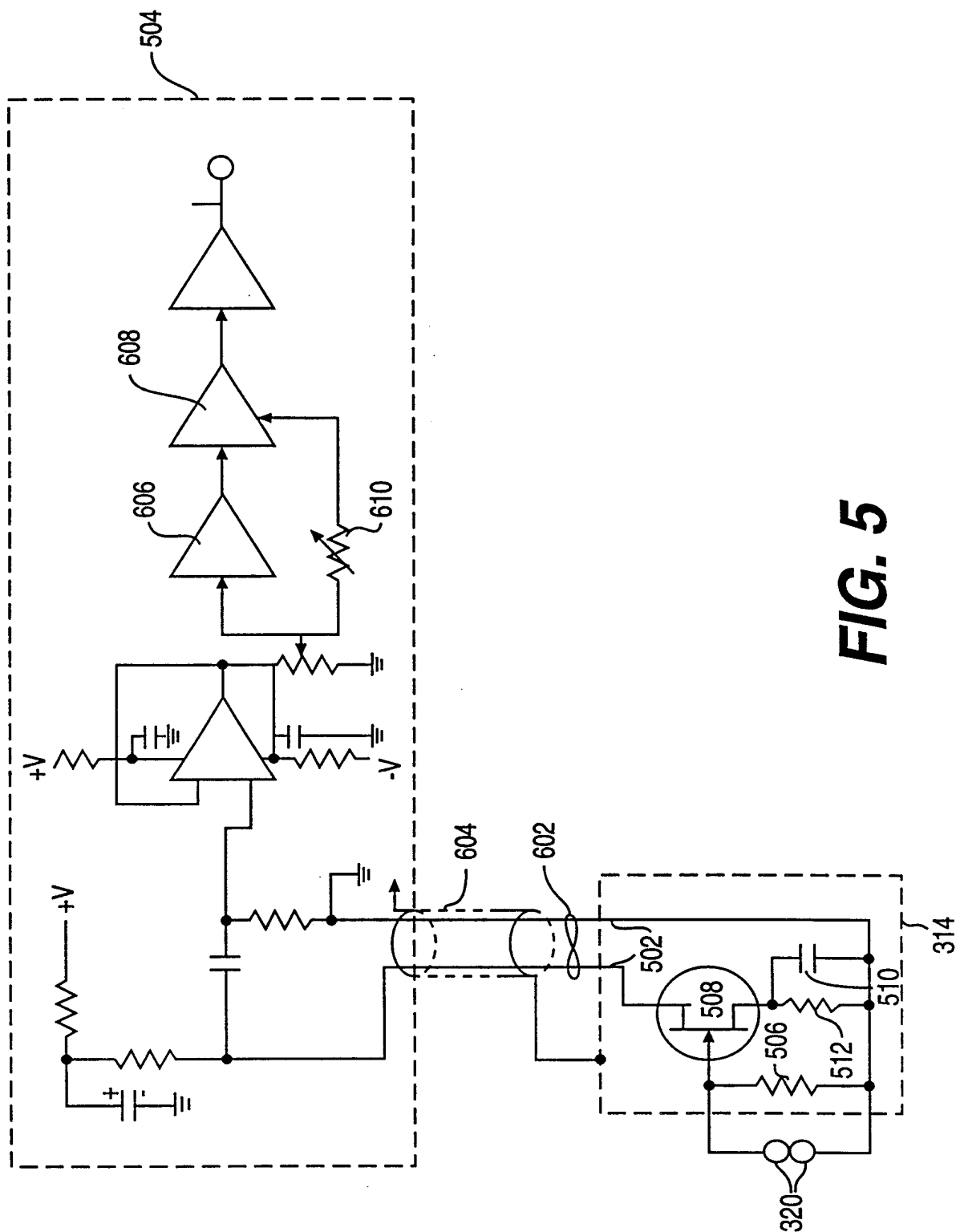
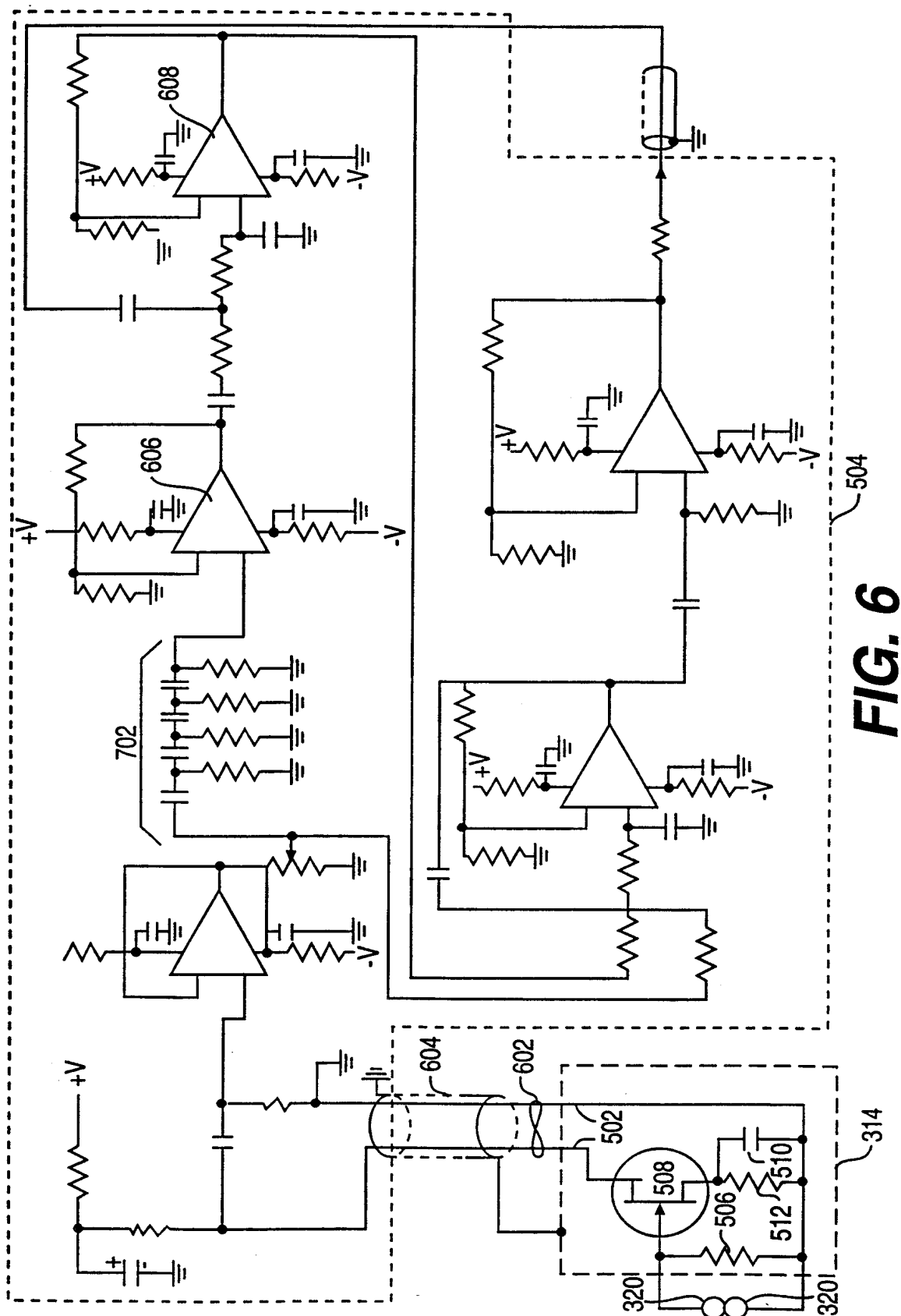


FIG. 5

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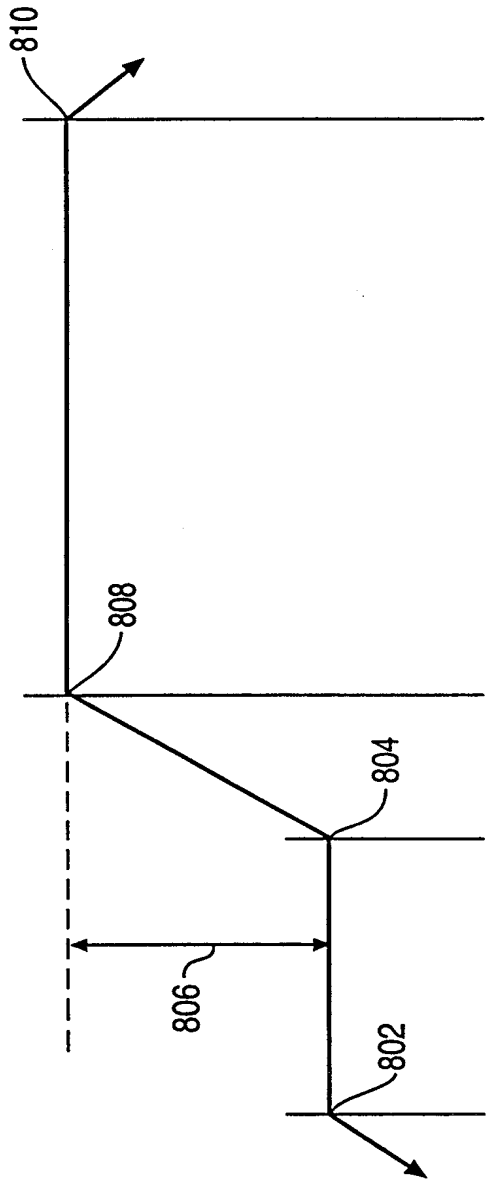


FIG. 7

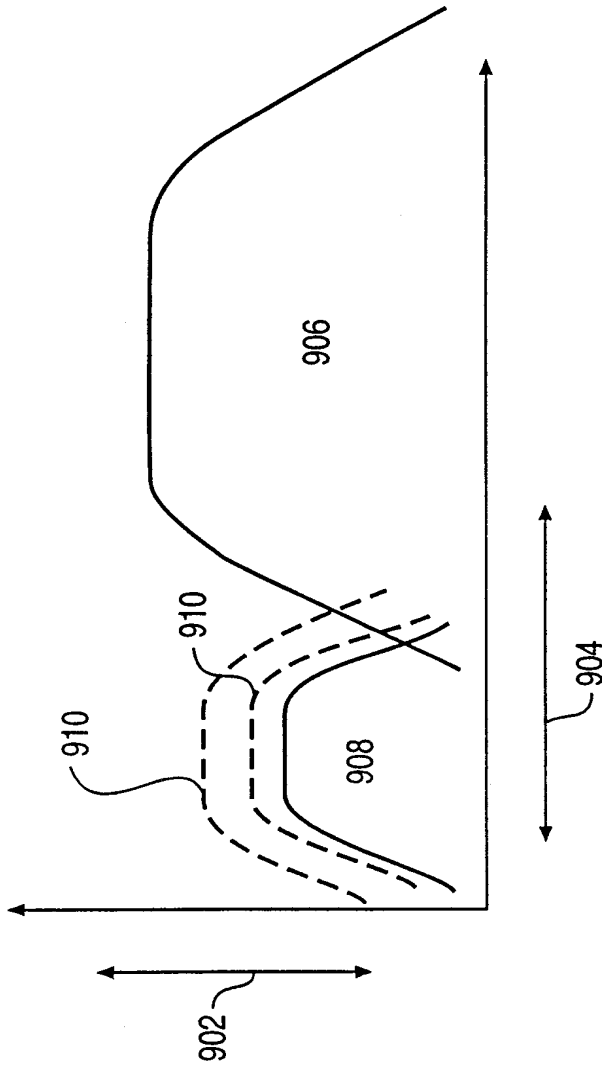


FIG. 8

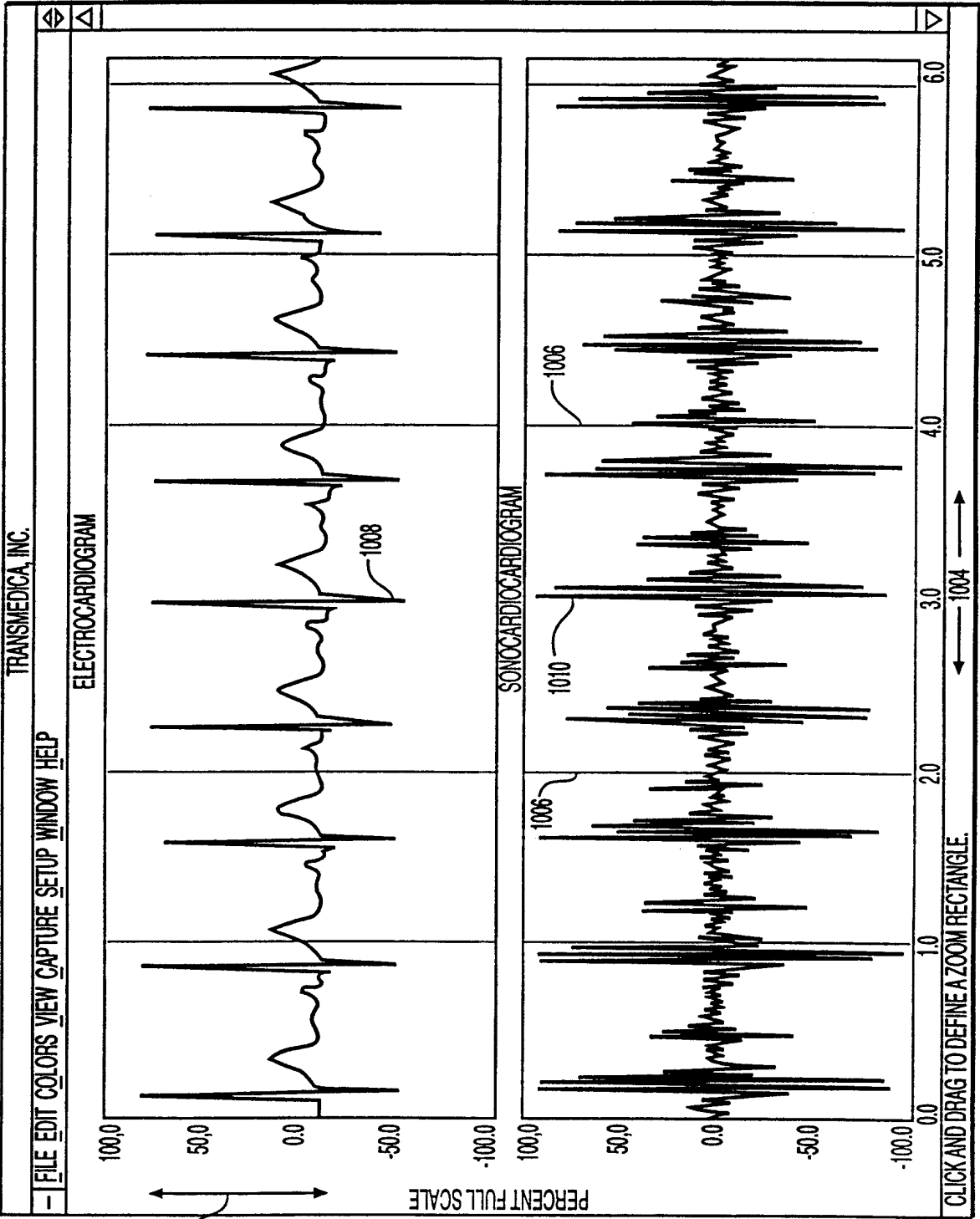
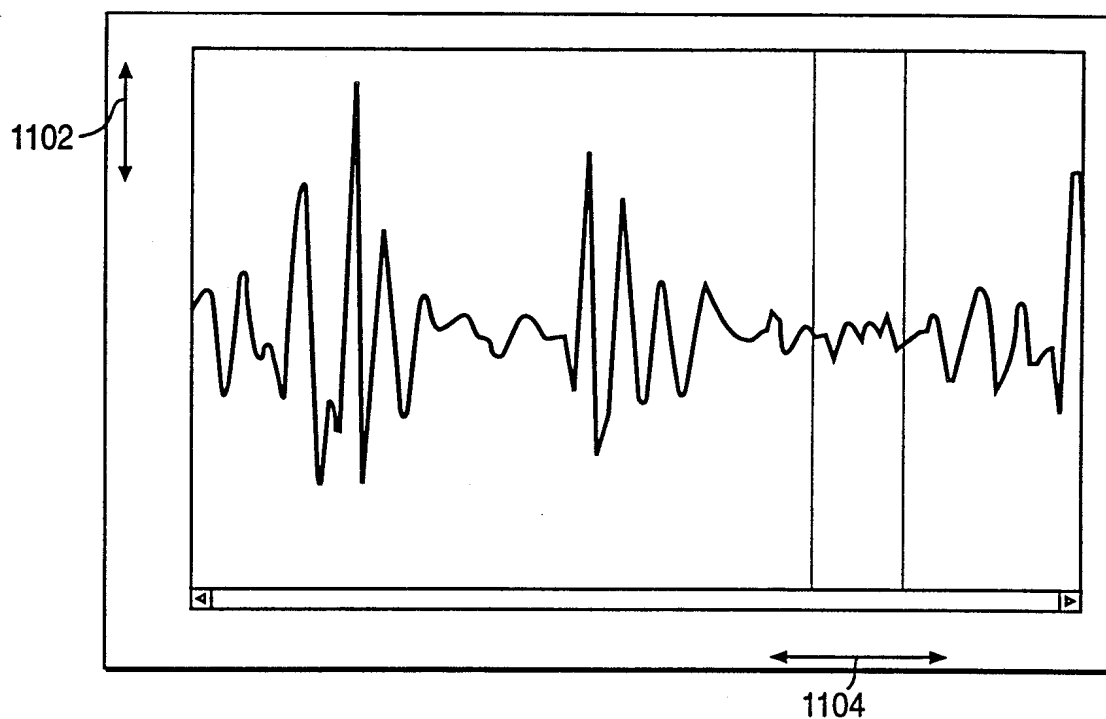
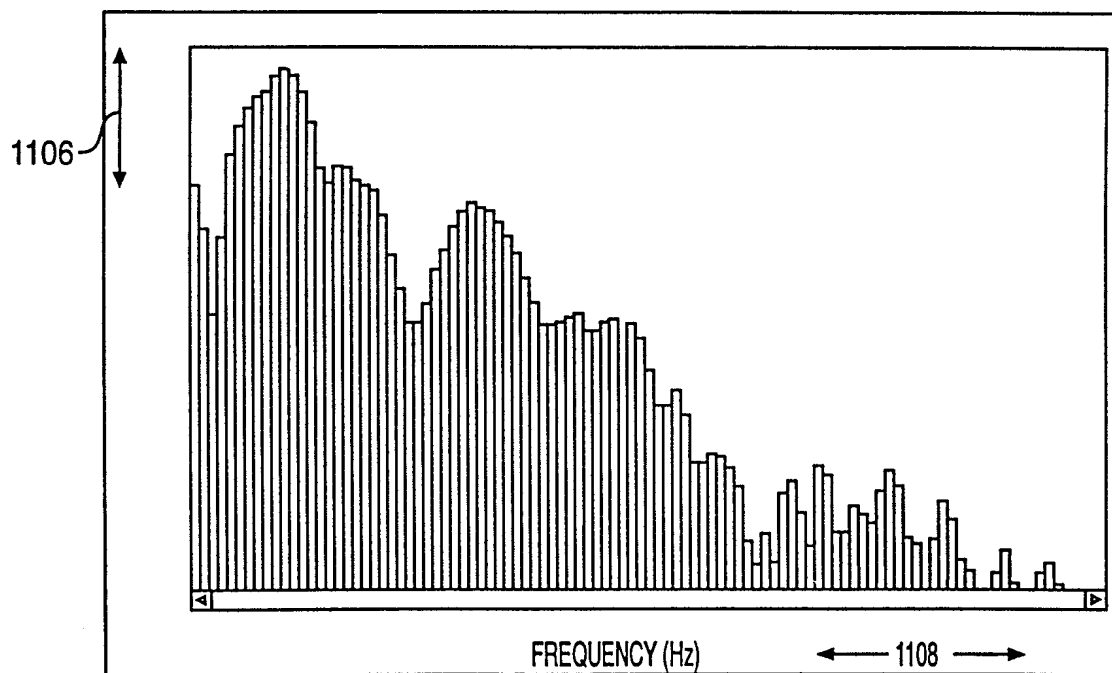
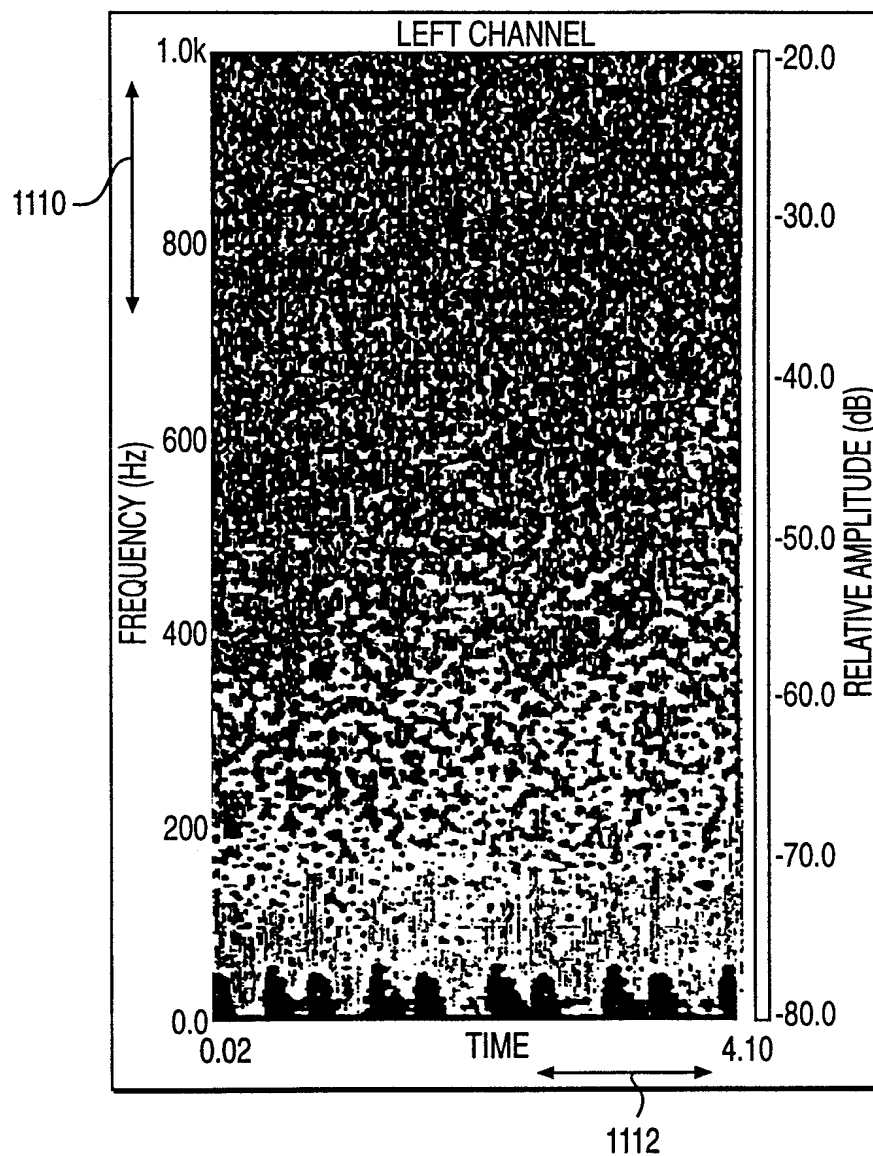


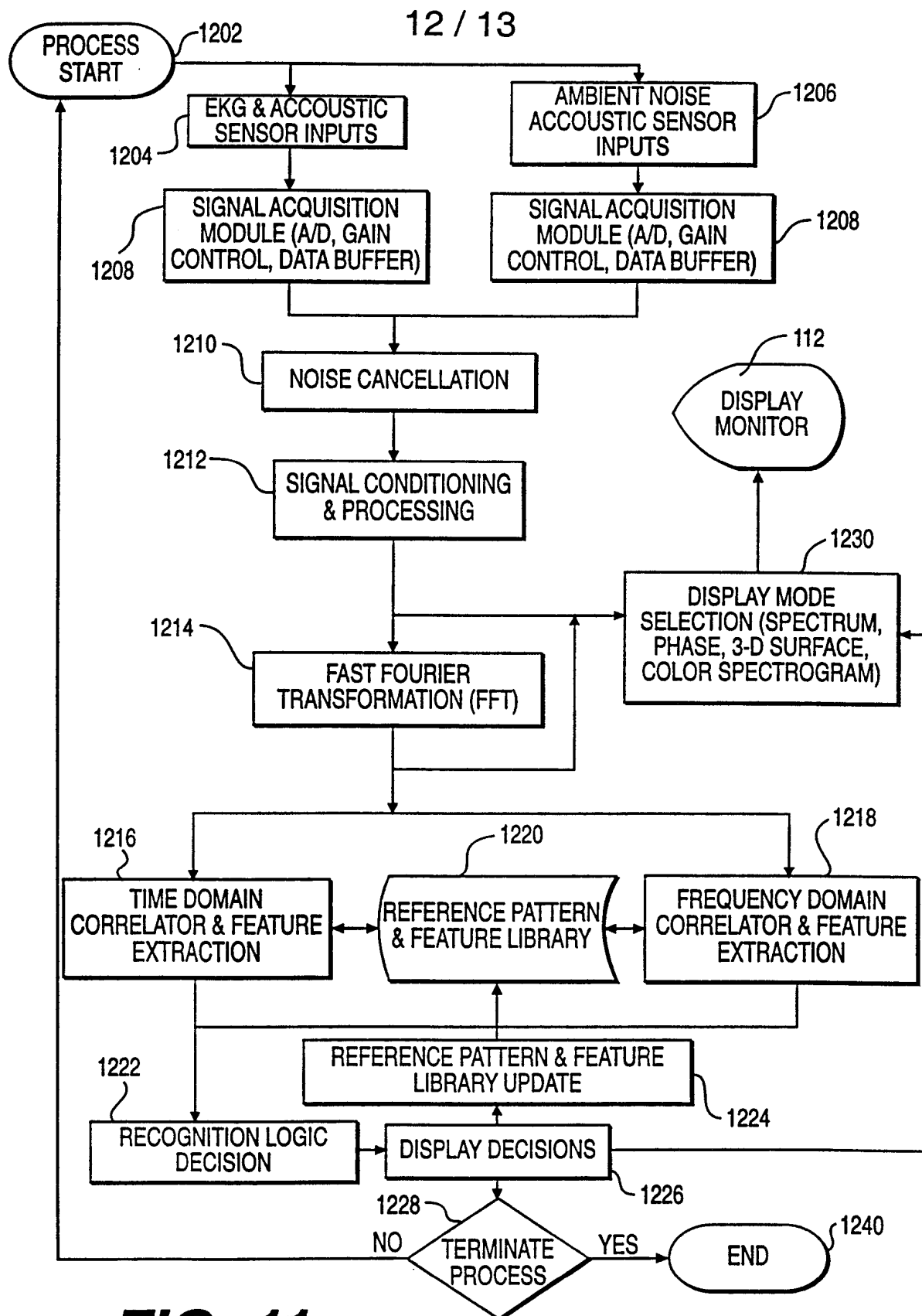
FIG. 9

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**FIG. 10a****FIG. 10b**

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**FIG. 10c**

**FIG. 11**

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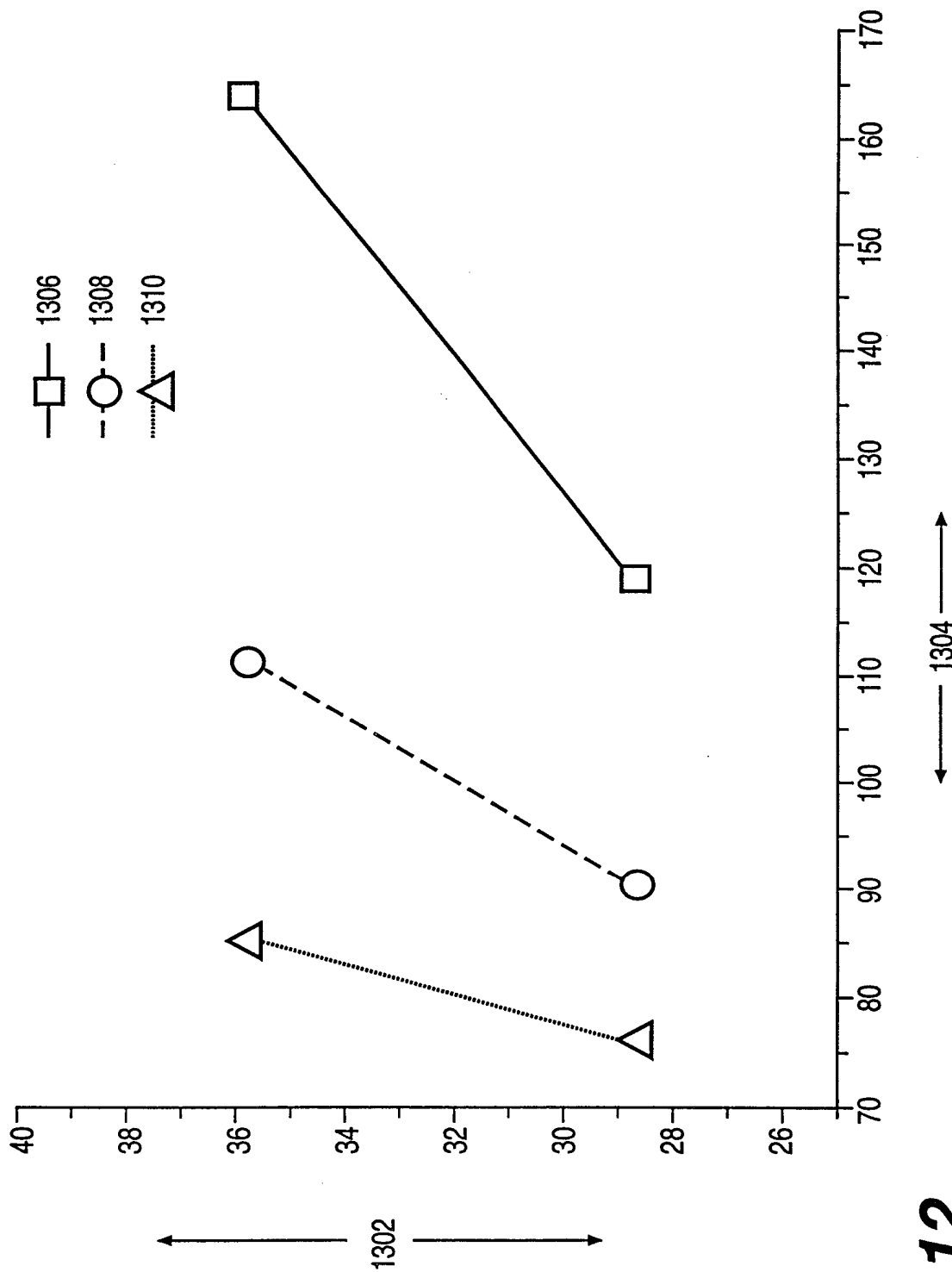


FIG. 12

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/21917

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B7/04

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 020 110 A (W.J. KASPARI) 10 December 1980	1-4, 7, 9-11, 14, 25, 26, 32, 34-37, 39, 43-45, 48, 50-52, 60-62, 65, 69 6, 47, 55 57, 58
A	see page 3, line 4 - line 37	
A	see page 7, line 11 - page 9, line 18	
	see page 12, line 24 - page 17, line 17 --- -/--	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search

7 April 1998

Date of mailing of the international search report

17/04/1998

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Authorized officer

Rieb, K.D.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/21917

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	see column 4, line 41 - column 5, line 17	32-37
A	see column 6, line 5 - column 7, line 28	43,58
A	see column 8, line 5 - line 44	65,67
	see column 11, line 56 - column 12, line 55	

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A	see column 1, line 25 - line 53	25-28
A	see column 4, line 1 - line 63	32-36,39
A	see column 9, line 9 - column 10, line 45	40,43-46
A	see column 10, line 66 - column 11, line 24	55,56, 65,67,69
	see column 13, line 64 - column 15, line 31	

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A	see column 6, line 19 - column 9, line 20	38-43

A	US 5 205 295 A (B. DEL MAR ET AL.) 27 April 1993	1,14, 16-20, 25,35
A	see column 9, line 46 - column 11, line 44	36,38-42

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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